for each subject enrolled. Additionally, a team of 4 clinical monitors has completed a thorough review of the charts and records for each subject that will be included in our PMA submission. As part of the monitors' review, the data contained in the electronic database was verified, and a comprehensive listing of all subjective complaints was compiled, which will be included in the PMA submission and the next progress report to FDA. The occurence of all events and complications as defined in Protocol NEV-97-001 have previously been reported to FDA. No serious adverse events related to the Nevyas Excimer Laser have occurred in the study. This was verified during the monitors' chart review.

- Schulman's IRB was selected as the reviewing IRB for the study because it was known that they complied with all the requirements of 21 CFR Part 56. We have obtained initial and continuing review for Protocol NEV-97-001, including submission of 6-month status reports and 12-month annual review reports, since its inception. The issue regarding approved sample size was discovered during the annual review process and was resolved to the IRB's satisfaction in an ongoing fashion.

FDA ITEM:

3. There was a lapse of IRB approval for the protocol NEV-97-001 from 8/3/2000 until 8/29/2000 according to IRB lapse notices and the IRB annual re-approval letter.

DR. NEVYAS' RESPONSE:

The annual report to the IRB was received by Schulman's IRB on July 28th, 2000. On August 1st, Schulman's requested additional information. This was faxed to Schulman's IRB on August 1st by our regulatory consultant (Dr. Barbara Fant). On August 7th, the same information was requested again by Schulman's IRB. Dr. Richard Sterling (of Nevyas Eye Associates) provided them with another copy of the same information that was supplied on August 1st. For unknown reasons, the additional information was not