

[REDACTED] sent Dr. Nevyas a notice dated August 1, 2000, **EXHIBIT #3**, to inform him that the revised protocol dated 7/8/98 in their possession indicated the [REDACTED] population was limited to [REDACTED]

Dr. Nevyas reported in a biannual report that was sent to [REDACTED] the number of [REDACTED] however, he failed to mention that the patient population had been increased by the FDA in Jan. 1999. Dr. Nevyas drafted a letter to [REDACTED] **EXHIBIT #4** dated 8/16/2000 explaining the increase in patient population. [REDACTED] reviewed the information from Dr. Nevyas and responded by letter **EXHIBIT #5** dated August 30, 2000 reapproving Dr. Nevyas' study for another year.

**2. The firm is not complying with the Investigator Agreement which was signed and dated by the Clinical Investigator at the beginning of the Clinical Study.**

**EXHIBIT #6** is an Investor Agreement which was signed by Dr. Herbert Nevyas, Sponsor/Clinical Investigator and Dr. Anita Nevyas-Wallace Co-Investigator. The agreement indicates, among other things, the clinical investigators agree to promptly report to the IRB all changes in the research activity. The clinical investigators failed to report the increase in the number of study patients, granted by the FDA, to the IRB in a prompt manner.

**3. There was a lapse of IRB approval for the protocol: [REDACTED] from 8/3/2000 until 8/29/2000 according to IRB lapse notices and the IRB annual re-approval letter.**

**EXHIBIT #7** is a reapproval letter from [REDACTED] dated 8/4/99 for Dr. Nevyas' study with an expiration date of 8/3/00. [REDACTED] wrote Dr. Nevyas on August 1, 2000, **EXHIBIT #3** indicating they had not received an update in the form of a report from him concerning the study. The letter also stated the IRB approval will lapse on 8/3/00. [REDACTED] wrote Dr. Nevyas for a second time on 8/7/2000

**EXHIBIT #8** indicating they still had not received any updates concerning the study. The letter also stated Dr. Nevyas should cease enrollment on [REDACTED] surgeries and if he chose to amend the protocol to request permission to do more [REDACTED] surgeries he could not begin scheduling the surgeries until the amendment was approved by the IRB. The laser refractive study log **EXHIBIT #2 pgs.12&13** show Dr. Nevyas continued performing [REDACTED] throughout the month of August 2000.