Nevyas Eye Assoc.
333 City Av.
Bala Cynwyd PA 19004
4/19,20,23-30, 5/1-
4,7,10/2001 RALS

From the date the first patient was treated under the IDE, August 28, 1997, until 11/2/98 Dr. Nevyas has treated [redacted]

According to Dr. Nevyas' refractive log **EXHIBIT #2**, from December 29, 1999 until April 20, 2001 [redacted] have been treated for [redacted]

Laser Eye surgery is performed at the aforementioned main address and at the office located at 1001-E Lincoln Drive West, Greentree Executive Campus, Marlton NJ 08053.

OBJECTIONABLE CONDITIONS OR PRACTICES:

At the conclusion of the inspection an FD-483 was issued and a discussion with management held. Dr. Herbert J. Nevyas, Clinical Investigator and Dr. Richard Sterling, Clinical Coordinator attended the meeting.

The following observations refer to the Investigational Device Exemption (IDE) Protocol# [redacted] for the indicated study, "[redacted]

1. **There was no documentation to show that the CI notified the IRB about all amendments, changes or significant deviations to the protocol [per IRB requirements] prior to implementation.**

   For example, the FDA granted your firm an increase in the number of subjects you could treat with your investigational device on Jan. 20, 1999. IRB Annual Review dated 7/29/00 does not indicate the IRB knew about population increase. The IRB did not approve the population increase until August 28, 2000, 20 months later.

Dr. Nevyas uses a national IRB, [redacted] for his clinical research study.
EXHIBIT #1 is a letter from the FDA CDRH, Division of Ophthalmic Devices to Dr. Herbert J. Nevyas which among other things granted him an increase in the number of clinical research study subjects to [redacted]