DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administrati
2098 Gaither Road
Rockville MD 20850

JAN - 7 1999

Herbert J. Nevyas, M.D.
Nevyas Eye Associates
Delaware Valley Laser Surgery Institute
2 Bala Plaza
333 City Avenue
Bala Cynwyd, Pennsylvania 19004

Dear Dr. Nevyas:

During the period of October 6 through November 2, 1998, Nevyas Eye Associates was visited by Mr. Ronald Stokes, an investigator from the Food and Drug Administration's (FDA) Philadelphia District Office. The purpose of that visit was to inspect your activities as a sponsor and clinical investigator of studies of laser assisted in situ keratomileusis (LASIK) for the treatment of myopia, with or without astigmatism, with the Sullivan Excimer Laser, Nevyas model, to determine if they complied with applicable FDA regulations. Excimer lasers are devices as that term is defined in Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

The inspection was conducted under a program designed to ensure that data and information contained in requests for Investigational Device Exemptions (IDE), Premarket Approval Applications (PMA), and Premarket Notifications [510(k)] are scientifically valid and accurate. Another objective of the program is to ensure that human subjects are protected from undue hazard or risk during the course of scientific investigations.

Our review of the inspection report submitted by the district revealed deviations from Title 21, Code of Federal Regulations, (21CFR), Part 812 - Investigational Device Exemptions and Part 50 - Protection of Human Subjects and Section 520(g) of the Act. The deviations noted during the inspection were listed on form FDA-483, "Inspectional Observations," which was presented to and discussed with you at the conclusion of the inspection. We acknowledge receipt of a November 30 response to the deviations from your consultant, Barbara S. Fant, Pharm. D.

It was noted on the form FDA-483 that two subjects had undergone simultaneous bilateral LASIK surgery prior to IDE approval for bilateral treatment. The response states that the original conditional approval of your IDE, dated 8/7/98, had included simultaneous bilateral surgery but that this approval had been rescinded for all Sullivan laser users on 10/3/97. Enclosed with the response was a copy of a letter to Dr. Everette Beers, Office of Device Evaluation (ODE), from Dr. Richard H. Sterling dated 10/23/97, which notes that two surgeries had been performed under the IDE study but that no additional bilateral procedures would be performed until specific IDE approval had been received. Dr. Beers confirmed that it had been assumed by Dr. Nevyas and other excimer investigators that IDE approval included bilateral