DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
US Food and Drug Administration Rm. 900 US Customhouse, 2nd and Chestnut Sts. Phila. PA 19106 (215) 597-4390	4/19,20, 23-30, . . 5/1-4,7, 10/2001 FEI NUMBER [redacted]

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO [redacted]

FIRM NAME	STREET ADDRESS
Medical Director	[redacted]
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
[redacted]	Sponsor/Clinical Investigator

DURING AN INSPECTION OF YOUR FIRM I OBSERVED:

The following observations refer to the Investigational Device Exemption (Protocol # [redacted]) for the indicated study, [redacted] with an [redacted]er in the Surgical Treatment of Refractive errors: Myopia with and without Astigmatism"

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

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.

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

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE *(Print or Type)*	DATE ISSUED
	[redacted]	[redacted]	May 10, 2001