DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER
US Food and Drug Administration
900 US Customhouse
2nd & Chesenut Sts.
Phila PA 19106
(215) 597-4390

NAME OF INDIVIDUAL TO WHOM REPORT ISSUED
TO: [redacted]

PERIOD OF INSPECTION
10/6,7,8,13,14,15,20,22,23,26,
27,30 - 11/2/98

TITLE OF INDIVIDUAL
Medical Director

TYPE ESTABLISHMENT INSPECTED
Clinical Investigator

FIRM NAME
[redacted]

NAME OF FIRM, BRANCH OR UNIT INSPECTED
SAME

STREET ADDRESS
[redacted]

STREET ADDRESS OF PREMISES INSPECTED
SAME

CITY AND STATE *(Zip Code)*
[redacted]

CITY AND STATE *(Zip Code)*
SAME

DURING AN INSPECTION OF YOUR FIRM I OBSERVED:

The following observations refer to the Investigational Device Exemptio[redacted] for the indicated study, "[redacted] with a[redacted]n the Surgical Treatment of Refractive errors: Myopia with and without Astigmatism"

1[redacted] was performed on IDE[redacted] and [redacted] on 8/28/97 prior to the actual approval date.

2[redacted] received Myopic[redacted] Enhancement on 9/25/97 OD (right eye) prior to the date approval was given to perform enhancements.

3. Consent form fo[redacted] was not dated. There was no way of determining whether consent was obtained before or aft[redacted] surgery to the right eye on 12/4/97, due to lack of a date next to the patients' signature.

4. Consent forms for[redacted] were signed and dated (2/20/98) one day after Myopic[redacted] surgery to the right eye was performed (2/19/98).

5[redacted] had [redacted] for Myopia on 8/13/98, however, the patient information and consent form, which was approved for use by the IRB on 7/17/98, was not present in the patient file or made available upon request.

6[redacted] had[redacted]nts performed for a condition that is not indicated in protocol [redacted]. Additionally, the procedures were performed with a laser that is not indicated in the study and the surgery was performed at a location that is not identified in the protocol.

7. 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].

SEE REVERSE OF THIS PAGE [redacted]

DATE ISSUED
11/2/98