[redacted]

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

[redacted], built the [redacted] for [redacted] however, [redacted] owns it. He was responsible for submitting the information for the IDE, in conjunction with [redacted] and eventually Pre-Market Approval for the device. He is therefore a Sponsor/Clinical Investigator.

[redacted] has retained the services of [redacted] Pharm D., President of [redacted] as a monitor and consultant for his clinical research, **EXHIBIT #3.** She has made a site visit which is reflected on the Monitor's Log, **EXHIBIT #4**, and also prepared a Monitoring Report, **EXHIBIT #5.** Ms Fant is responsible for ensuring that [redacted] and [redacted] did read, understand, sign and adhere to the Investigator Agreement forms, **EXHIBITS 6&7.**

[redacted] is the Institutional Review Board [redacted] IRB) that is used by [redacted] to oversee the IDE clinical study, Protocol [redacted] beginning 8/20/97, **EXHIBIT #8.** A list of the IRB members is included, **EXHIBIT #9 and** it should be noted that [redacted] is listed as an alternate member.

[redacted] is performed at the [redacted] location and at the office located at [redacted] and [redacted]

OBJECTIONABLE CONDITIONS OR PRACTICES/DISCUSSION WITH MANAGEMENT:

At the conclusion of the inspection a F[redacted] was issued and a discussion with management held. [redacted], Clinical Investigator, [redacted], Co-Investigator [redacted] Clinical Coordinator attended the meeting.

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

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