

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

According to a letter dated August 27, 1997, **EXHIBIT #8** from the IRB, [REDACTED] is required, in addition to other items, to report to the IRB any new advertisements, recruiting material, serious adverse events, amendments or changes to the protocol or significant protocol deviations.

Observation # 6 represents a significant protocol deviation and should have been reported to the IRB for approval prior to implementation.

**VOLUNTARY CORRECTIONS:**

Previous inspection on 6/30/97 of this facility revealed the firm used the [REDACTED] laser to perform [REDACTED] eye surgery without an approved IDE. The firm now performs [REDACTED] eye surgery under an approved IDE.

**PROMOTION AND DISTRIBUTION:**

**EXHIBIT #63** is a hard copy of an advertisement that aired for several weeks by a local news station. [REDACTED] stated this was not necessarily advertisement for the [REDACTED] surgical procedure and therefore, did not need to be submitted to the IRB for approval.

**ATTACHMENTS:**

1. FDA-482, Notice of Inspection dated 10/6/98
2. Copy of assignment
3. FDA-483, Inspectional Observations