[redacted]
22,23,26,27,30-
11/2/98 RALS

[redacted] for treatment of Myopia was not approved until January 14, 1998 according to a letter to [redacted] from the FDA dated the same **EXHIBIT #10.**

EXHIBIT #11 indicates [redacted] had [redacted] on 8/28/97. **EXHIBIT #12** shows [redacted] also had [redacted] on 8/28/98. These procedures were performed well before approval was granted.

[redacted] stated he had been doing this procedure previously and no one had told him the procedure couldn't be performed as of 8/28/97.

I indicated to [redacted] that [redacted] dated March 18, 1997 was part of his initial IDE submission and did include provisions for simultaneous bilateral [redacted] on page 24 of **EXHIBIT #13.** However, the entire IDE submission was disapproved as per a letter dated 5/18/97 from the FDA to [redacted], **EXHIBIT #14** . Conditional approval was not granted until 8/7/97, **EXHIBIT #15,** and did not specify simultaneous bilateral [redacted] could be done. That procedure was specifically approved in a letter January 14, 1998.

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

Myopic [redacted] enhancements/retreatments was not approved under the IDE until October 3, 1997 according to a letter from the FDA to [redacted] dated the same **EXHIBIT #16.** [redacted] received [redacted] on 9/25/97 OD (right eye) **EXHIBIT #17.** [redacted] Co-Investigator performed this procedure and stated [redacted] told her it was okay to perform myopic [redacted] enhancements and did not know it was not approved. [redacted] stated he thought it was okay because he thought the procedure was approved.