

4/19, 20, 23-30, 5/1-4, 7, 10/2001

Finally, the letter stated IRB approval lapsed 8/3/00.

On 8/16/2000 [REDACTED] drafted a letter to [REDACTED] indicating the FDA had granted him an increase in the study patient population
EXHIBIT #4. [REDACTED] sent [REDACTED] a letter dated August 30, 2000 reapproving the study effective the same date for another year
EXHIBIT #5.

I explained to [REDACTED] that he did not have IRB coverage from 8/3/2000 and until 8/29/00. [REDACTED] stated his consultant, [REDACTED] was ill for several months and she normally took care of report submittals and updates which is why the firm was tardy with reporting updates. I indicated to [REDACTED] that either he or his consultant should have a back-up plan for such emergencies which could happen at any time. He stated a back-up plan would be drafted and implemented as soon as possible.

VOLUNTARY CORRECTIONS:

1. Simultaneous [REDACTED] was performed on [REDACTED] and [REDACTED] on 8/28/97 which was prior to the actual approval date.

According to [REDACTED], he was not aware that [REDACTED] was not approved and could not be performed. He stated this observation represents a misunderstanding between the FDA and him.

[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. There were no violations of this type observed during the current inspection.

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

[REDACTED], Co-Investigator performed this procedure and stated her father, [REDACTED], told her it was okay to perform myopic [REDACTED]. Both investigators indicated they did not know it was not approved. [REDACTED] stated he thought it was okay and remembers getting verbal approval from someone at FDA in Rockville Md. I indicated to [REDACTED] that in the future he should obtain documentation for all approvals given. There were no violations of this type observed during the current inspection.