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

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

I explained to Dr. Nevyas that he did not have IRB coverage from
8/3/2000 and until 8/29/00. Dr. Nevyas stated his consultant,
Barbara Fant 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 Dr. Nevyas 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.

<u>**VOLUNTARY CORRECTIONS:**</u>

1. ▓▓▓▓▓▓▓▓▓▓▓▓▓▓▓▓▓▓▓▓▓▓▓▓**was performed on IDE**
   patient▓▓▓▓▓**and patient** ▓▓▓▓▓**on 8/28/97 which was**
   prior to the actual approval date.

According to Dr. Herbert Nevyas, he was not aware that▓▓▓▓ was
not approved and could not be performed. He stated this
observation represents a misunderstanding between the FDA and
him.

Dr. Herbert J. Nevyas 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. **IDE Patient** ▓▓▓▓▓**received** ▓▓▓▓▓**Enhancement on**
   9/25/97 OD (right eye) prior to the date approval was given to
   perform enhancements.

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