

PERSONS INTERVIEWED AND INDIVIDUAL RESPONSIBILITIES:

On 4/9/97, Joseph L. Despina, CSO & myself presented our credentials and an FDA-482 was issued to **Edward J. Sullivan**, President, ExSull, Inc., Drexel Hill, PA on the premises of LaserLink, 108 Chesley Dr., Madison Bldg., Media, PA 19063. The firm's actual office is located at 319 Lombardy Road, Drexel Hill, PA 19026., but Mr. Sullivan was very adamant that we not meet at that location, since this site is also his residence and our presence disrupts his family life. He suggested that Mr. Despina and myself meet him at another firm, which he is a part owner, LaserLink, an internet service provider firm. Repeated attempts to schedule a subsequent meeting with Mr. Sullivan (via my leaving numerous messages on his voice mail) were unsuccessful. Mr. Sullivan would not commit to a date and time, when he returned my repeated phone calls, and in some instances did not even return my phone calls. Only after inadvertently meeting him at one of his client's (on 6/25/97), did he then agree to see me at his ExSull, Inc., Drexel Hill location. On 6/26/97, I presented my credentials and issued another FDA-482, Notice of Inspection, to Mr. Sullivan. On 6/27/96, an FDA-483 was issued to Mr. Sullivan, and was present during discussions with management.

GUARANTEES & LABELING AGREEMENTS:

Mr. Sullivan maintained that there are no labeling agreements, and that the only labeling on the devices is that required by any regulations for warning or cautionary labeling for the safe operation of lasers.

TRAINING PROGRAM:

Mr. Sullivan stated that he is the only employee of the firm. He stated that he has not had any formal training in GMP regulations.

RAW MATERIALS AND COMPONENTS:

Mr. Sullivan stated that all of the devices (except the first excimer laser at the Kremer Eye Associates) have a [REDACTED] In addition, he stated that most of his client's had purchased the integrated laser enclosure from [REDACTED]