EXHIBIT 4

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Why I do not recommend Dr. Anita Nevyas-Wallace!

After damaging my eyes with Refractive Surgery, Drs. Herbert Nevyas and Anita Nevyas-Wallace sued to silence me. These are my medical and legal experiences with Anita Nevyas-Wallace of Nevyas Eye Associates.

My intention with this site is to update and further prove all allegations I brought against Anita Nevyas as documented on my previously owned website LasikSucks4u.com and now LasikDecision.com. I would also like to show how I believe the courts were misled in many of their decisions and/or opinions regarding my med mal lawsuit Morgan v. Nevyas and the current Nevyas v. Morgan lawsuit.

More Articles...

- Herbert Nevyas 2007 Letter To NJ DMV
- Before The Nevyas' Study
- Nevyas' Investigational Study
- Nevyas' Investigational Laser
- Nevyas' Promotion of an Investigational Device
- FDA Inspection Reports of the Nevyas' Facility
- Nevyas' Deviation From Standard of Care
- Nevyas' Court Depositions In My Case & Others

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Before The Nevyas' Study

It started with Ed Sullivan, the guy who built the 'Nevyas Laser', a man already under scrutiny by the FDA...

"Ed Sullivan, doing business as ExSull, Drexel Hill, Pa, has been put on notice by the FDA that the agency regards him "clearly as a manufacturer with multiple manufacturing sites" subject to FDA rules and regulations and, if he makes another one of these excimer lasers "which are unapproved devices," he will be in violation of the federal Food, Drug and Cosmetics Act and subject to legal penalties, according to top-ranking FDA officials within the national Division of Enforcement." [as written in The Journal of Refractive Surgery - Volume 11 (5) * September/October 1995 * News, which was removed from the url address http://www.slackinc.com/eye/jrs/vol115/news1.htm].

And the FDA knew that! From the affidavit Herbert Nevyas submitted to the FDA, it tells of Ed Sullivan building their laser. However, documents show Mr. Sullivan in teleconferences and meetings with the doctors and their laison with the FDA well **after** this article was written.

After I received inspection reports even less redacted from the FDA regarding inspections of the Nevyas' facility, the FDA promised "to do what they could to help me", but then refused after copies of the inspection reports were returned. In fact Les Weinstein, the CDRH Ombudsman, outright told me (through his secretary) he could no longer have any communication with me. It seems to me (based on my communications with the FDA) that the FDA was more concerned with being sued by the Nevyases for the information released, then by doing the right thing.

The inspection reports of Sullivan's facility below were obtained via the Freedom Of Information Act. Regardless of these reports and the articles written concerning 'Homegrown Lasers", is this what the FDA considers "protecting the public's safety"?

Click PAGE # to open pages in new window

PAGE 1 - *Previous inspection, 5/16/96, was a follow up to a Warning Letter issued on 8/17/95. The Warning Letter informed the firm that the FDA considered ExSull, Inc., to be a manufacturer of a Class III medical device, that was both adulterated and misbranded, in that there were no approved PMA or IDE for any of the devices and that the firm itself was not registered as a medical device manufacturer.*

PAGE 2 - *Mr. Sullivan stated that "he called the FDA and was sent material relating to the building of "custom devices", and that the FDA person he had spoken to over the telephone assured him that it was okay to build them in the Doctor's office".*

PAGE 3 - *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.,*

PAGE 4 - *Mr. Sullivan stated that he did not have any standard procedures for assembling the device. He stated that the device components are delivered to each physician's office, where he then assembles the compete excimer laser. He informed me that he will then test the laser,* ***but that he does not have any performance specifications, written assembly instructions or quality control tests.***

PAGE 5 - *and that any involvement by Mr. Sullivan in a sale, would depend on the nature of the sale. He would not elaborate on that statement, but explained that it means that he is not involved in every sale.*

PAGE 6 - *Mr. Sullivan informed me that he has not contracted to build any additional units, since he assembled the device for* [redacted] *in October 1996. On 6/26/97, Mr. Sullivan showed me a copy of an IDE for that same client* [redacted], *Mr. Sullivan explained that he was working on the document, and an examination of the IDE showed that the unit had been used to treat at least* [redacted] *patients, without an approved IDE. Mr. Sullivan would not allow me to copy this document, and stated that the FDA already has this IDE on file.*

PAGE 7 - *Mr. Sullivan did state that he will be publishing an article with a Dr. Herbert Nevyas, regarding the use of the ExSull, Inc., excimer laser for treatment of a patient with an irregular cornea, due to an eye injury.*

PAGE 8 - *According to Mr. Sullivan, this entire process (the exchange of laser beam requirements and the design specifications) is all done via telephone or personal visits, and* ***he does not have any written records of the design specifications****. He stated that each individual physician should have those records. Mr. Sullivan stated that he knew of no injuries with the device.* ***He did say that in theory the laser would have some patients possibly experiencing overcorrection, but that the majority would experience a slight undercorrection, which might require additional treatment****. In addition, he explained that there has been no hazing or scaring, with the devices. He stated that the physicians handle all of the complaints from the patients, and that he is not aware of any major complications.*

PAGE 9 - *Mr. Sullivan informed me that he designed the hardware for the "beam shaper" or "beam sculptor", as well as, the software that controls that hardware. He stated that his program was written in [redacted] and that three versions have been made, of that software. He informed me that he had no documentation or procedures for upgrading or changing the program (at the [redacted]. In addition, he could not provide any information regarding which of the software versions are in any of the particular devices, stating that he did not keep any of those records.*

PAGE 10 - *Mr. Sullivan gave his permission for me to observe the calibration procedure. I was allowed to examine the optical compartment, including the "beam*

shaper" or "beam sculptor", designed by Mr. Sullivan. Mr. Sullivan would not let me photograph this part of the device.

PAGE 11 - *He informed me that he is only a consultant, and that each device he assembles is considered a "Custom Device". He confirmed that he did not have any medical device manufacturing records, such as Master Device Record or Device History Record. I asked Mr. Sullivan if the firm had a Device Master Record or Device History Record. He responded that he considers himself a consultant, and that he does not keep any records of design specifications, manufacturing specifications or a device History Record. He stated that each of the physicians might have any documentation for the specifications or design, for their device.*

PAGE 12 - *During the inspection, Mr. Sullivan stated that the firm's computer, used to store all of the business records, had experienced a "hard drive crash", in the winter of 1996. He explained that consequently all records from 1994 to December 1996 have been lost.*

PAGE 13 - *He stated that he does not keep any repair or service log books, or a records of any complaints regarding the performance of the laser, by the physicians.*

PAGE 14 - *There are no Exhibits with this EIR, due to the unavailability of records at the firm.*

PAGE 15 - *The observations noted in this FDA-4B3 are not an exhaustive listing of objectionable conditions.* FDA 483 issued.

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The FDA issued warning letters regarding the lasers Sullivan built, but **STILL** allowed doctors to further modify and use these devices on people considering LASIK!

Warning Letter 1 <> Warning Letter 2

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Nevyas' Investigational Study

The following letters are from the FDA to Drs. Herbert Nevyas and Anita Nevyas-Wallace throughout their investigational study, and after their study was terminated. Despite continued deficiencies as noted below, the FDA kept granting the Nevyases Approvals for their study. Based on documents received during my med mal and the current Nevyas v. Morgan lawsuits, **I believe the Nevyases constantly misrepresented themselves and their study to both Schullman Associates (the Nevyases IRB) and the FDA:**

All BLUE font on this page designate links to documents which should open in new window.

May 1997

IDE Disapproval Letter from the FDA to Nevyases dated 05/08/97:

PAGE 1 - *The Food and Drug Administration (FDA) has reviewed your investigational device exemptions (IDE) application. We regret to inform you that your application is disapproved and you may not begin your investigation. Our disapproval is based on the deficiencies listed below.*

PAGE 2 - Deficiencies listed.

PAGE 3 - *Please explain the low effectiveness and safety outcomes achieved in your prior clinical studies and specify what steps you are taking to improve your results. Your refractive and visual outcomes were reported at one month as: MSRE for low myopes. < 57% were within ID and < 35% were within 0.5D; less than 60% achieved BUCVA > 20/40: complication and adverse events occurred in > 2% of the cases.*

PAGE 4 - *Please provide your agreement (or justification for not agreeing) that retreatments done to improve refractive outcome are NOT considered as treatment failures, whereas retreatments done to achieve resolution of an adverse event ARE considered as treatment failures.*

PAGE 5 - *Your description of study procedures, examination conditions and techniques is not adequate. Please provide a detailed description of each procedure, test and instrument to be used in the study.*

PAGE 6 - *For your follow-up visit schedule, the text on page 20 of the protocol appears to be inconsistent with the chart on page 43 of the protocol. In addition, please justify your statement on page 20 that measurement of corneal topography will be at the discretion of the investigator.*

View **ALL PAGES** pdf document.

July 1997

Letter from the FDA to Nevyases dated 07/29/97 to cease using Laser:

PAGE 1 - *FDA is aware that a number of physicians are using lasers for refractive surgery to treat patients even though there is no PMA or IDE in effect for their lasers. Based on the results of our investigations, we believe that you are currently using your laser to treat patients.*

PAGE 2 - *Accordingly, on July 28, 1997, we called you to notify you that use of your excimer laser to treat patients would violate the Act and requested that, if you are presently using the laser to treat patients, you immediately cease doing so.*

Nevertheless, FDA does intend to consider any use of your laser to treat patients after the close of business July 28, 1997 unless and until the agency approves an IDE for your device to be grounds for disapproval of your IDE.

PAGE 3 - *We also want you to know that if FDA approves your IDE application, you would be able to use your laser to perform only specific procedures on a limited number of subjects to demonstrate the safety and effectiveness of your laser for those procedures. Studies conducted under such an IDE would be subject to all IDE regulations. See 21 C.F.R. Part 812. For example,* ***you would be prohibited from promoting and commercializing the laser, and from representing that the device is safe and effective.***

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August 1997

'Conditional' Approval Letter from the FDA to Nevyases dated 08/07/97:

PAGE 1 - *Your application is conditionally approved because you have not adequately addressed deficiency #2 cited in our May 8, 1997 disapproval letter.*

Also, we are in receipt of your certification (Amendment 4 received August 1, 1997) that you have not used the laser as of the close of business on July 28, 1997, and that you will not use the laser unless and until FDA approves the IDE applic2tion for your device

PAGE 2 - *This approval is being granted on the condition that, within 45 days from the date of this letter, you submit information correcting the following deficiencies.*

PAGE 3 - Deficiencies listed.

PAGE 4 - Deficiencies listed.

PAGE 5 - *We have enclosed the guidance document entitled "Sponsor's Responsibilities for a Significant Risk Device Investigation" to help you understand the functions and duties of a sponsor.*

View **ALL PAGES** pdf document.

October 1997

Letter from the FDA to Nevyases dated 10/03/97:

PAGE 1 - *We acknowledge receipt of your institutional review board (IRB) approval (supplement 3). Supplement 4 responds to our conditional approval letter of August 7, 1997 and requests: an increase crease in treatment range from -6.75 ID to -22 ID: approval to study*

simultaneous bilateral treatment; and, approval to retreat approximately 125 patients previously treated with this laser prior to IDE approval.

PAGE 2 - *Requests for additional subjects for enhancements for prior clinical patients will be evaluated as additional data is submitted to support stability of the procedure.*

PAGE 3 - *You agree that you will not perform retreatment procedures for subjects initially treated under this IDE. Retreatment (enhancement) for subjects initially treated under this IDE is appropriate only after your preliminary data demonstrate safety and indicate the time point of stability of the procedure. You may begin retreatment procedures only after FDA has approved your retreatment study plan and data to support stability.*

PAGE 4 - **PAGE 5** - **PAGE 6** - **PAGE 7** - **PAGE 8** - **PAGE 9** - **PAGE 10** - Deficiencies listed.

PAGE 11

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December 1997

Approval Review Letter from the FDA to Nevyases:

PAGE 1 - *The Food and Drug Administration (FDA) has reviewed the supplement to your investigational device exemptions (IDE) application. Your application remains conditionally approved because your supplement adequately addressed only deficiency 2 cited in our October 3, 1997 letter.*

This approval is being granted on the condition that, within 45 days from the date of this letter, you submit information correcting the following deficiencies.

PAGE 2 - *You are reminded that prior to a request for expansion beyond 150 subjects, you should provide adequate responses to deficiencies 5 16 in our letter of October 3, 1997.*

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FDA INVESTIGATIONAL STUDY AFFIDAVIT

The following pages are an Investigator Agreement issued by the FDA to a Sponsor/Investigator of an investigational study. Nevyas refused to sign...

PAGE 1 - Investigator agreement signed by Anita Nevyas-Wallace

PAGE 2 - Investigator agreement signed by Herbert Nevyas

PAGE 3 - "*I informed Mr. Kane, that Mr. Sullivan told me that the excimer laser that he would build, is considered a custom device and would not be regulated by the FDA. Mr. Sullivan completed the assembly of the laser in the fall of 1995, and the first patient was treated (using LASIK) in January 1996.*"

PAGE 4 - "*I did not maintain any written records of the design specifications, nor did I receive any written design specifications from Mr. Sullivan.*"

PAGE 5 - "*This patient is not part of the patient population included in my IDE submission. I have treated a total of 252 patients, from January 1996 to the present date (6/30/97).*"

PAGE 6 - "*I affirm that the information on this and the previous pages, is the best of my ability.* ***I have read, but would not sign this affidavit.***"

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Nevyases were issued an FDA483:

PAGE 1 - *There was no documentation to show that the CI notified the IRB about all amendments, changes of significant deviations to the protocol [per IRB requirements] prior to implementation. For example, the FDA granted your firm an increase in the number of subjects you could treat with your investigational device on Jan. 20, 1999. IRB. Annual Review dated 7/29/00 does not indicate the IRB knew about population increase. The IRB did not approve the population increase until. August 28, 2000, 20 months later.*

The firm is not complying with the Investigator Agreement which was signed and dated by the Clinical Investigator at the beginning of the Clinical Study.

There was a lapse of IRB approval for the protocol: NEV-97-001 from 8/3/2000 until 8/29/2000 according to IRB, lapse notices and the IRB annual reapproval letter.

January 1998

Approval Review Letter from the FDA to Nevyases:

PAGE 1 - *In your "Substudy for Same-Day Versus Different Day LASIK Treatment for Fellow Eyes": a. Please revise your informed consent document rider for same day surgery to state that the second eye will be rescheduled if there is a complication or an adverse event with the first eye.*

PAGE 2 - *Your statement in the rider to the informed consent document that "...There have been no failures or malfunctions of the Willis Excimer Laser", should be removed or altered. It may unduly influence potential same day fellow eye surgery candidates into believing that the Nevyas Excimer Laser cannot fail. FDA recommends that you remove this statement or alter it to read: "There have been no failures or malfunctions of the Nevyas Excimer Laser to date."*

PAGE 3 -

April 1998

Letter from the FDA to Nevyases dated 04/01/98 Re: Pre Market Approval (PMA):

PAGE 1 - Offers suggestions from the FDA should the Nevyases submit their PMA.

PAGE 2 -

May 1998

Approval Letter from the FDA to Nevyases dated 05/14/98 Re: Contrast Sensitivity & Increased 'Subjects':

PAGE 1 - 'Conditional' approval for substudy and increase of 'subjects'.

PAGE 2 - *We acknowledge your request in your original IDE (dated March 18, 1997) to conduct a study at one site with 400 eyes low myopia and 590 eyes high myopia for each of two*

investigators (single site total of 1980 eyes or 990 subjects). We believe that adequate safety information has been provided to allow the initiation of your study with a small expansion of an additional 75 subjects (150 eyes). We will allow you to expand to the full number of subjects for this study (990) after you have received approval of supplements addressing the following deficiency from our letter of October 3, 1997 (enclosed). No additional expansions of your IDE will be granted until supplements containing the following information are approved:

PAGE 3 - *You should also give serious consideration to the following items which are considered essential for the analysis of your data for the purposes of determining safety and effectiveness for a future PMA application: Deficiencies 5 through 16, excluding deficiency 14, in our letter of October 3, 1997.*

July 1998

"Conditional" Approval Letter from the FDA to Nevyases:

PAGE 1 - *FDA cannot approve your request as proposed because you have not shown stability of manifest refraction, and you have not presented sufficient detail for your hyperopic retreatment. FDA will conditionally approve, however, an expansion to include myopia and myopic astigmatism retreatments at this time.*

PAGE 2 - *This approval is being granted on the condition chat, within 45 days from the date of this letter, you submit your agreement to: 1. conduct the investigation within the modified limit, i.e., retreatment for myopia or myopic astigmatism only: 2. extend the minimum time between the initial operation and the retreatment to 3 months; and. 3. retreat only eyes which are "white and quiet" and in which refractive stability has been documented with two manifest refractions taken at least 30 days apart at less than 1 diopter of—change, confirmed by topography..*

PAGE 3 -

September 1998

Approval Letter from the FDA to Nevyases:

PAGE 1 -

PAGE 2 -

Nevyases' Co-Investigators (dated 10/01/98)

I started some time ago to contact the doctors on this **LIST** the Nevyases sent to the FDA, as being co-investigators. Three of those contacted who responded have never even heard of the Nevyases.

December 1998

Approval Letter from the FDA to Nevyases:

PAGE 1 -

PAGE 2 -

January 1999

Deviations of Nevyas Eye Associates, As Stated In Letter from the FDA dated 01/07/99:

PAGE 1 - *Our review of the inspection report submitted by the district revealed deviations from Title 21, Code of Federal Regulations, (21 CFR), Part 812 - Investigstional Device Exemptions and Part 50 - Protection of Human Subjects and Section 520(g) of the Act. The deviations noted during the inspection were listed on form FDA-483, "Inspectional Observations," which was presented to and discussed with you at the conclusion of the inspection.*

PAGE 2 - *Use of the Summit laser at your Marlton, New Jersey site for off-label procedures is not included in your IDE protocol. Moreover, enhancements approved under your IDE do not include hyperopic procedures. It is therefore considered a protocol violation to retreat subjects of your IDE study using the Summit laser and performing hyperopic LASIK.*

PAGE 3 - *While your Marlton, New Jersey site has a Summit laser, the advertisement does not specify a location. Future advertisements should specify the location(s) of approved lasers, as the enclosed advertisement would not be appropriate for soliciting subjects for your IDE study. All promotional materials designed to solicit participants or to inform subjects about the IDE study need to be approved by the reviewing IRB.*

Approval Letter from the FDA to Nevyases dated 01/20/99:

PAGE 1 - *Please be aware of the following: In Table 1-1, the data appear to be quite scattered, with some subjects actually increasing in sensitivity during glare (e.g., see BC & CB at 3 cycles per degree (CPD)), while others are severely compromised (see ZM). In order to reduce variability in the data in the contrast sensitivity study, the person administering the test should have experience in this test and the subjects should be well trained prior to testing.*

PAGE 2 - *We continue to be concerned that your ablation is likely to have multifocal properties, which means some light will be out of focus even at the best focal plane.*

November 1999

Request Letter from the FDA to Nevyases:

PAGE 1 - *1. Please separate IDE subjects from pre-IDE subjects in all of your tables, or report only on IDE subjects.*

PAGE 2 -

January 2001

Letter from the FDA to Nevyases Re: Non-Response To Request:

PAGE 1 - *The Food and Drug Administration (FDA) granted approval of your investigational device exemptions (IDE) application on August 7, 1997. As part of your responsibilities as sponsor of a significant risk device investigation, you are required to submit a progress report to FDA and to all reviewing institutional review boards (IRBs) on at least a yearly basis. We have not received a response to FDA's November 10, 1999 request for additional information regarding your August 1998 — August 1999 annual progress report (enclosed).*

PAGE 2 -

April 2001

Request Letter from the FDA to Nevyases:

PAGE 1 - *Please address the following questions/concerns, as well as provide the information requested in the tables enclosed with this letter.*

PAGE 2 - *8. With regard to your future PMA submission, you have indicated that only subjects treated with the "new centration technique" will be included in the PMA, and that you have selected the eyes treated between 2/19/98 and 11/22/99 as the cohort to support the safety and effectiveness of the device. We would like to clarify that data from all subjects treated, under the IDE should be included in the PMA. The main PMA cohort on which the decision of the safety and effectiveness of the device will mainly rest may be limited to all eyes treated with the new centration technique, but not to only those enrolled during a given period of time, as you appear to have suggested.*

PAGE 3 -

July 2001

Disapproval Letter from the FDA to Nevyases:

PAGE 1 - *The Food and Drug Administration (FDA) has reviewed the supplement to your investigational device exemptions (IDE) application proposing two new clinical protocols to evaluate the spherical ablation algorithm. We regret to inform you that your supplement is disapproved and you may not implement the change in your investigation. Our disapproval is based on the following deficiencies which, unless otherwise specified, relate to both protocols:*

PAGE 2 - *3. You have not provided in your protocol the methodology for performing any of the clinical evaluations. For each clinical evaluation, please specify the testing procedures and instruments that will be used, including the lighting conditions and charts you will use to measure distance vision and near vision, etc.*

PAGE 3 - *7. Your protocol states that subjects must have a best spectacle corrected visual acuity (BSCVA) of at least 20/40 in each eye in order to be enrolled in the study. Please be advised that while we find this criteria acceptable for subjects with high myopia (≥7 D MRSE), in order for subjects with low myopia (< 7 D MRSE) to be enrolled, we recommend a BSCVA of at least 20/25 in each eye. Please revise your protocol accordingly, or justify not doing so.*

PAGE 4 - *21. The Conclusion section of the consent form stares, "There is always a possibility of one or more late complications That were not known or anticipated at the time of this writing (1997)." It also states, "LASIK is investigational surgery and as such, it has not yet been completely and exhaustively studied by the FDA and medical researchers in this country." Please update the consent form as necessary in keeping with current knowledge including the additions previously mentioned. Please revise the second statement to Improve its accuracy: LASIK is no longer investigational, it has never (page 5) been studied by the FDA, and the FDA does not regulate LASIK, only the devices used for the procedure.*

PAGE 5 - *28. There are discrepancies in the way you refer to the protocols throughout the submission. For example, in the Introduction you refer to the new protocols as NEV-97-002 (Myopia/Myopic Astigmatism) and NEV-97-003 (Hyperopia/Hyperopic Astigmatism). However, the myopia protocol itself has been labeled with the protocol number NEV-01-002.*

To avoid confusion, please make all necessary revisions in any future submission to correct such discrepancies.

PAGE 6 - *With respect to the profiles of your ablated PMMA samples:*

PAGE 7 - *The deficiencies identified above represent the issues that we believe need to be resolved before your IDE application can be approved. In developing the deficiencies, we carefully considered the relevant statutory criteria for Agency decision-making as well as the burden that may be incurred in your attempt to respond to the deficiencies.*

PAGE 8 - *34. Please be advised that for possible future pre-market approval, although 300 eyes total are needed to support overall safety, data from approximately 125 eyes are needed to support each indication for which approval is being sought.*

August 2001

Supplement Disapproval Letter from the FDA to Nevyases:

PAGE 1 - *We regret to inform you that your supplement is disapproved and you may not implement the change in your investigation. Our disapproval is based on the following deficiencies: 1. An important function of the software in the device is to control the beam delivery hardware (iris size, slot movement, synchronizing iris/slot with laser pulses, etc.) in the creation of an ablation pattern. This area, however, is not discussed at all in the Software Requirement Specifications document.*

PAGE 2 - *The deficiencies identified above represent the issues that we believe need to be resolved before your IDE application can be approved.*

PAGE 3 -

February 2002

Nevyases Deviations and discrepancies continue almost 5 years into their study - Letter from the FDA to Nevyases:

PAGE 1 - *Please address the following, questions and concerns with regard to this submission, which also applied to the previous, delinquent, annual report as outlined in FDA's letter of April 10, 2001, and for which we never received a response:*

PAGE 2 - *5. Please provide tables (similar to those requested for initial treatments) and narrative summarizing the results of the IDE substudy of enhancements for 25 subjects/50 eyes that had undergone treatment prior to implementation of the IDE, and of the data from enhancements performed for eyes enrolled under the IDE. Please provide separate analyses for the first enhancement, second enhancement, etc.*

PAGE 3 - *1. Please note that, based on the stability analyses you have provided in this submission, we do not agree that the time point of stability is at 12 months postoperatively as you have indicated, and, in fact, may be earlier for some of the indications.*

PAGE 4 -

April 2002

IDE Deficiencies Request Letter from the FDA to Nevyases:

PAGE 1 - *1. You must still provide responses to deficiencies 1, 2, 3, and 5 froth our letter of February 6, 2002. 2. You did not provide the requested information in your response to deficiency 4.*

PAGE 2 - *4. In response to deficiency 8, you have indicated how you will verify your current accountability for visits that have already past. After your internal audit is complete and you have more insight as to the reasons for any problems with accountability, please directly address the original issue outlined in previous deficiency 8: please describe how you intend to improve subject follow-up and data reporting during the rest of the course of your IDE study.*

PAGE 3 - Attachment: *In a reply to Dr. Morris Waxler, FDA's Chief Medical Device Examiner, Dr. Herbert Nevyas states "Since the close of business on July 28, 1997, neither I nor anyone else has used the laser. I certify that, unless and until FDA approves the IDE application for that device, neither I nor anyone else will use the laser to treat patients. I have notified all of my employees, as well as anyone with access to the laser, that the laser may not and will not be used until there is an approved IDE in effect for that laser. I declare that to the best of my knowledge the foregoing is true and correct."*

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Nevyas' Investigational Laser

The following documents were submitted to the FDA from 1997 through 2001 regarding the "Nevyas Investigational (Black Box) Laser"

The laser was built by Ed Sullivan who, according to the excerpt below, was already under scrutiny by the FDA.

"Ed Sullivan, doing business as ExSull, Drexel Hill, Pa, has been put on notice by the FDA that the agency regards him "clearly as a manufacturer with multiple manufacturing sites" subject to FDA rules and regulations and, if he makes another one of these excimer lasers "which are unapproved devices," he will be in violation of the federal Food, Drug and Cosmetics Act and subject to legal penalties, according to top-ranking FDA officials within the national Division of Enforcement." [as written in The Journal of Refractive Surgery - Volume 11 (5) * September/October 1995 * News and was found at the url address: http://www.slackinc.com/eye/jrs/vol115/news1.htm">http://www.slackinc.com/eye/jrs/vol115/news1.l (no longer available).

Click PAGE # to open page in new window

NOTES: Page numbers with an "l" designate the page as landscape. All BLUE font on this page designate links. ***Some PDF documents may require a decrease in magnification for better clarity.***

PDF Documents (for high speed or download)

To view ALL DOCUMENTS listed below in one PDF (two parts), click HERE.

1997 Reports

PAGE 1 - Prohibition of promotion and other practices. - *21 CFR. § 812.7*

PAGE 2 - Protocol NEV-97-001: Myopia with or without astigmatism - Study Procedures.

PAGE 3 - Protocol NEV-97-001: Inclusion/Exclusion Criteria.

PAGE 4 - IDE Supplement - Question/Response.

PAGE 5 - Protocol NEV-97-001: Ethical and regulatory considerations.

PAGE 6 - Protocol NEV-97-001: Complications, Adverse Events, & Serious/Unanticipated Adverse Device Effects.

PAGE 7 - Protocol NEV-97-001: Inclusion/Exclusion Criteria Revision.

PAGE 8 - Protocol NEV-97-001: Screening for Refractive Surgery Eligibility.

PAGE 9 - **PAGE 10** - Protocol NEV-97-001: Clinical Study Data Submitted to FDA.

1998 Reports

PAGE 1 - **PAGE 2** - **PAGE 3** - **PAGE 4** - **PAGE 5** - **PAGE 6** - **PAGE 7** - **PAGE 8** - **PAGE 9** - **PAGE 10** - **PAGE 11** - **FULL** - Protocol NEV-97-001: Study IDE Supplement Annual Report

PAGE 1 - **PAGE 2** - **PAGE 3** - **FULL** - Protocol NEV-97-001: Study IDE Annual Report Supplement

PAGE 1 - **PAGE 2** - **PAGE 3** - **FULL** - Protocol NEV-97-001: Study Changes, Progress towards PMA Approval, Safety & Efficacy for Study Eyes (*Notice the 100% for cumulative UCVA of 20/40 or better, the 0 counts for the BSCVA worse than 20/40 or better, or for the BSCVA worse than 20/25, 6 months after my surgery*).

1999 Reports

PAGE 1 - **PAGE 2** - **FULL** - The FDA states "*We continue to be concerned that your ablation is likely to have multifocal properties, which means that some light will be out of focus even at tine best focal plane*".

PAGE 1 - **PAGE 2** - **PAGE 3** - **FULL** - Safety & Efficacy for Study Eyes, Page 1 (*Notice the 100% for cumulative UCVA of 20/40 or better, the 0 counts for the BSCVA worse than 20/40 or better, or for the BSCVA worse than 20/25, 1 1/2 years after my surgery*). The charts on pages 2 and 3 also do not show adverse events or complications.

2001 Reports

PAGE 1 - **PAGE 2** - **FULL** - Protocol Deviations & Summary of Complications and Adverse Events.

PAGE 1 - **PAGE 2** - **PAGE 3** - **FULL** - Nevyas Investigational Study charts submitted to the FDA.

PAGE 1 - The FDA states ***"There was no documentation to show that the CI notified the IRB about all amendments, changes or significant deviations to the protocol [per IRB requirements] prior to implementation"***; ***"The firm is not complying with the Investigator Agreement which was signed and dated by the Clinical Investigator at the beginning of the Clinical Study"***; and ***"There was a lapse of IRB approval for the protocol: NEV-97-001 from 8/3/2000 until 8/29/2000 according to IRB, lapse notices and the IRB annual reapproval letter"***.

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FDA Inspection Reports of the Nevyas' Facility

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NOTES: Page numbers with an "l" designate the page as landscape. All BLUE font on this page designate links.

FDA Issued Inspection Report of Nevyas Eye Associates facility dated 11/02/1998:

PAGE 1 - *There was no documentation to show that the Cl notified the IRB about all amendments, changes or significant deviations to the protocol [per IRB requirements].*

PAGE 2 - *Previous inspection on 6/30/97 of this facility revealed the firm continued to use the laser to perform eye surgery without an approved IDE, planned to use the laser or new treatment procedures not included in the firms disaproved IDE and verified that the firm had received a disapproval letter from CDRH/ODE notifying them that use of the laser to treat patients was a violation of the law.*

PAGE 3 - **PAGE 4** - charts

PAGE 5 - *The current inspection revealed Clinical Investigator currently performs Myopic procedures under an approved IDE however, procedures are being performed on IDE patients prior to approval date, the date is missing on a consent form, consent forms were signed by patients after surgery date and procedures were performed on IDE patients which are outside the IDE with an unidentified laser at an unauthorized location.*

PAGE 6 - Persons interviewed, individual resposibilities, & operations.

PAGE 7 - [Redacted] *initial IDE submission was disapproved May 8, 1998. He was granted conditional approval on August 7, 1998. As* [Redacted] *addressed various issues presented in letters from FDA CDRH/ODE he was granted more uses of the IDE.*

PAGE 8 - [Redacted] *built the* [Redacted] *for* [Redacted] *however,* [Redacted] *owns it. He was responsible for submitting the information for the IDE, in conjunction with and eventually Pre-Market Approval for the device. He is therefore a Sponsor/Clinical Investigator.*

PAGE 9 - *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.*

PAGE 10 - *Consent form for* [Redacted] *was not signed. There was no way of determining whether consent was obtained before or after surgery to the right eye on 12/4/97, due to lack of a date next to patients' signature.*

PAGE 11 - [Redacted] *had* [Redacted] *enhancements performed which is a condition not indicated in the* [Redacted]. *Additionally, the procedures were performed with a laser that is not indicated in the study and the surgery was performed at a location that is not identified in the protocol.*

PAGE 12 - *There was no evidence of a patient information and consent form in the file for this hyperopic enhancement.*

PAGE 13 - *There was no documentation to show that the CI notified the IRB about all amendments, changes or significant deviations to the protocol [per IRB requirements].*

PAGE 14 - *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.*

PAGE 15 - **PAGE 16** - **PAGE 17** - **PAGE 18** - **PAGE 19** - Lists exhibits included with inspection report.

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FDA Issued Inspection Report of the Nevyas' facility dated 05/10/2001:

PAGE 1 - *The firm is not complying with the Investigator Agreement which was signed and dated by the Clinical Investigator at the beginning of the Clinical Study.*

PAGE 2 - *An inspection conducted on 12/2/96 revealed the firm had assembled a single excimer laser and was using it to perform* [Redacted] *eye surgery on at least 120 patients without an approved IDE.*

PAGE 3 - Persons interviewed, individual resposibilities, & operations.

PAGE 4 - *According to a letter from the FDA to* [Redacted] *dated 1/20/99* ***EXHIBIT #1****, the investigation is still limited to one location, listed in bold above however, the population has grown to 1015 subjects (2030 eyes):*

PAGE 5 - *For example, the FDA granted your firm an increase in the number of subjects you could treat with your investigational device on Jan. 20, 1999. IRB Annual Review dated 7/29/00 does not indicate the IRB knew about population increase. The IRB did not approve the population increase until August 28, 2000, 20 months later.*

PAGE 6 - ***EXHIBIT #6*** *is an Investor Agreement which was signed by* [Redacted] *Sponsor/Clinical Investigator and* [Redacted] *Co-Investigator. The agreement indicates, among other things, the clinical investigators agree to promptly report to the IRB all changes in the research activity. The clinical investigators failed to report the increase in the number of study patients, granted by the FDA, to the IRB in a prompt manner.*

PAGE 7 - *I explained to* [Redacted] *that he did not have IRB coverage from 8/3/2000 until 8/29/2000.* [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.

PAGE 8 - [Redacted] *stated it may appear that patients signed the consent forms one day after surgery however, this is certainly not the case and is not the way things are normally done. He indicated this was a mistake made by someone on his staff.*

PAGE 9 - ***There was no documentation to show that the CI notified the IRB about all amendments, changes or significant deviations to the protocol [per IRB requirements].*** *This observation was carried forth to the current listing of objectionable conditions or practices.* ***See FDA-483 observation #1 listed above on page #4 of this report.***

PAGE 10 - *All changes made to the protocol were documented by the investigator, dated, maintained with the protocol, however all changes were not approved by the IRB* ***(see FDA-483 observation #1 listed on page 4 of this report).***

PAGE 11 - *According to records reviewed, the investigator did submit and obtain IRB approval of the protocol, modifications to the protocol* ***(except as noted in FDA-483 OBSERVATION #1),***

PAGE 12

- Lists exhibits included with inspection report.

PAGE 13 - **PAGE 14** - **PAGE 15** - **PAGE 16** - **PAGE 17**

- Nevyases response to inspection.

"All adverse experiences have been reported to the sponsor-investigator, FDA, and IRB in accordance with 21 CFR Part 812", and "*The occurence of all events and complications as defined in Protocol NEV-97-001 have previously been reported to FDA. No serious adverse events related to the Nevyas Excimer Laser have occurred in the study".*

According to **deposition by Anita Wallace**, my visual problems post-lasik was not considered a complication or adverse event (I disagree!), even though she claimed the data regarding my situation was reported to the FDA. The charts submitted to the FDA listing adverse events and complications do NOT show data relevant to the number of medical malpractice claims filed against them during their study.

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The 2nd inspection resulted in an FDA483 issued by the FDA.

Although the records requested via the FDA's Freedom Of Information Act were redacted (edited), the FDA stated:

"There is too much information the general public should not be aware of, not only in the Nevyas' study, but in all studies". - Les Weinstein, CDRH Ombudsman

This second set was obtained from the FDA's Philadelphia Office, and included not only the Nevyas' facility of 05/2001, but that of Ed Sullivan (Exsull), builder of their laser (see above). The inspection was 2 years after the article written in the Journal of Refractive Surgery (Fall Issue - 1995):

Inspection Report of the Nevyas' facility dated 1 (less edited):

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