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.

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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 accurate, to 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 ($\geq$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."*