FILED
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Civil Administration

PHILADELPHIA COURT OF COMMON PLEAS

PETITION/MOTION COVER SHEET

CONTROL NUMBER:
01-09062102
(RESPONDING PARTIES MUST INCLUDE THIS NUMBER ON ALL FILINGS)

FOR COURT USE ONLY	
ASSIGNED TO JUDGE:	ANSWER/RESPONSE DATE:

Do not send Judge courtesy copy of Petition/Motion/Answer/Response. Status may be obtained online at http://courts.phila.gov

November Term, 2003
Month *Year*
No. 946

Nevyas, et al

vs.

Morgan, et al

Name of Filing Party:
Dominic J. Morgan, pro se

(Check one) ☐ Plaintiff ☑ Defendant
(Check one) ☐ Movant ☑ Respondent

INDICATE NATURE OF DOCUMENT FILED:

☐ Petition *(Attach Rule to Show Cause)* ☐ Motion
☐ Answer to Petition ☑ Response to Motion

Has another petition/motion been decided in this case? ☑ Yes ☐ No
Is another petition/motion pending? ☐ Yes ☑ No
If the answer to either question is yes, you must identify the judge(s):
Maier, Rogers

TYPE OF PETITION/MOTION *(see list on reverse side)*	PETITION/MOTION CODE *(see list on reverse side)*
	MTMIS

ANSWER/RESPONSE FILED TO *(Please insert the title of the corresponding petition/motion to which you are responding):*
Response to Miscellaneous Motion

I. CASE PROGRAM

Is this case in the *(answer all questions)*:

A. COMMERCE PROGRAM

Name of Judicial Team Leader: _____

Applicable Petition/Motion Deadline: _____

Has deadline been previously extended by the Court?
☐ Yes ☐ No

B. DAY FORWARD/MAJOR JURY PROGRAM — Year _____

Name of Judicial Team Leader: _____

Applicable Petition/Motion Deadline: _____

Has deadline been previously extended by the Court?
☐ Yes ☐ No

C. NON JURY PROGRAM

Date Listed: _____

D. ARBITRATION PROGRAM

Arbitration Date: _____

E. ARBITRATION APPEAL PROGRAM

Date Listed: _____

F. OTHER PROGRAM: _____

Date Listed: _____

II. PARTIES ***(required for proof of service)***

(Name, address and ***telephone number*** of all counsel of record and unrepresented parties. Attach a stamped addressed envelope for each attorney of record and unrepresented party.)

Leon Silverman, Esquire
Stein & Silverman, P.C.
230 South Broad Street, 18TH Floor
Philadelphia, PA. 19102
215-985-0255

Maureen Fitzgerald, Esquire
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2 Liberty Place
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215-841-8400

Dominic J. Morgan, pro se
1038 E. 18th Street
Chester, PA 19013
610-364-3367

III. OTHER

By filing this document and signing below, the moving party certifies that this motion, petition, answer or response along with all documents filed, will be served upon all counsel and unrepresented parties as required by rules of Court (see PA. R.C.P. 206.6, Note to 208.2(a), and 440). Furthermore, moving party verifies that the answers made herein are true and correct and understands that sanctions may be imposed for inaccurate or incomplete answers.

_____ _____ Dominic J. Morgan, pro se 07/08/09

(Attorney Signature/Unrepresented Party) *(Date)* *(Print Name)* *(Attorney I.D. No.)*

The Petition, Motion and Answer or Response, if any, will be forwarded to the Court after the Answer/Response Date. No extension of the Answer/Response Date will be granted even if the parties so stipulate.

30-1061B

Case ID: 031100946
Control No.: 09062101

Instructions for Completing Petition/Motion Cover Sheet

A Petition/Motion Cover Sheet must be attached to all Petitions, Motions, Answers or Responses filed, except for Discovery Motions and Motions for Extraordinary Relief. Sanctions will be imposed if the Cover Sheet is inaccurately completed.

Please Note the following:

1. ANSWER or RESPONSE DATE. The Motion Clerk shall enter the "Answer" or "Response" Date on the Cover Sheet. All Responses to Motions and Answers to Petitions must be filed with the Prothonotary and submitted to the Motion Clerk on or before the Response Date. **Note:** Summary Judgment Motions have a 30 day Response period. Except for those Motions identified in Phila.Civ.R. *208.3(a) and (b), all other Motions have a 20 day Response period.
2. ARGUMENT DATE. The Motion Clerk shall enter the Argument Date and location on the Cover Sheet, as appropriate.
3. CONTROL NUMBER. The Motion Clerk shall assign a Control Number to all Petitions and Motions. The Responding parties must enter this Control Number on the Cover Sheet accompanying their Answer or Response.
4. NATURE OF DOCUMENT FILED. The filing party must check whether the document being filed is a Petition (in which case a Rule to Show Cause Order must be attached), a Motion, an Answer to a Petition, or a Response to a Motion. The parties must indicate whether another Petition or Motion is outstanding or has been decided and, if so, must identify the Judge(s) to whom such prior Petitions or Motions had been assigned.
5. PETITION OR MOTION TYPES. The parties must utilize the following Petition or Motion Codes and Types (and the Motion Clerk is authorized to change a filing party's designation to reflect the correct Petition or Motion Code and Type):

CODE	MOTIONS
MTSAL	Motion for Additional Distribution of Sale Proceeds
MTPHV	Motion for Admission Pro Hac Vice
MTSVR	Motion for Alternative Service
MTAMJ	Motion to Amend Judgment
MTAMD	Motion to Amend Pleading
MTGAL	Motion to Appoint Guardian Ad Litem
MTAPC	Motion for Appointment of a Conservator
MTMCF	Motion for Approval and Distribution of Minor's Compromise
MTWRD	Motion for Approval & Distribution of Wrongful Death & Survival Action
MTAPS	Motion to Approve Transfer of Structured Settlement
MTADH	Motion for Assessment of Damages Hearings
MTAMV	Motion to Auction Motor Vehicles
MTBIF	Motion to Bifurcate
MTCIA	Motion to Certify Order for Interlocutory Appeal
MTCNM	Motion to Change Name
MTCLC	Motion for Class Action Certification
MTCMP	Motion to Compel Discovery
MTCPS	Motion to Compel Payment of Settlement
MTCOM	Motion to Complete Terms of Sheriff's Sale
MTCST	Motion to Confirm Settlement
MTCNS	Motion to Consolidate Actions
MTCON	Motion for Continuance
MTCOR	Motion for Coordination of Actions
MTCRT	Motion to Correct Record
MTCNF	Motion for Counsel Fees
PTDOM	Motion for Delay Damages
MTDJT	Motion to Demand Jury Trial
DPROB	Motion to Determine Preliminary Objections
MTDSC	Motion to Discontinue Case
MTDIS	Motion to Dismiss for Forum Non Conveniens
MTDCN	Motion to Disqualify Counsel
MTEMG	Emergency Motion
MTEST	Motion to Enforce Settlement
MTJDG	Motion for Entry of Default Judgment
MTJNP	Motion for Entry of Judgment of Non Pros
MTSUP	Motion for Entry of Supersedeas
MTEXP	Motion for Expungement of Record
MTEOT	Motion for Extension of Time to file Certificate of Merit
MTEXT	Motion for Extension of Time to answer/ respond)
PTEXR	Motion for Extraordinary Relief
MTNPT	Motion to File Nunc Pro Tunc
MTFUS	Motion to File Under Seal
PTFMV	Motion to Fix Fair Market Value
MTINT	Motion for Interpleader
MTINV	Motion to Intervene
MTIOP	Motion to Invalidate Opt-Outs (Class Action cases)
MTJAD	Motion to Join Additional Defendant
MTJPL	Motion for Judgment on the Pleadings
MTJUR	Motion for Jury Out of Time
MTLIM	Motion in Limine
MTMJS	Motion to Mark Judgment Satisfied
MTMVR	Motion to Obtain Motor Vehicle Records
MTOPN	Motion to Open/Strike Confessed Judgment
MTPAR	Motion for Partition
MTPIC	Motion for Payment into Court
MTPRE	Motion to Pay Rent into Escrow Account
MTSYS	Motion to Postpone Sheriff's Sale
PTTMF	Motion for Post Trial Relief
MTPCD	Motion for Pre-Complaint Discovery
PRINJ	Motion for Preliminary Injunction
MTPSA	Motion for Preliminary Settlement Approval (Class Action Cases)
MTPDE	Motion to Preserve Documents and Evidence
MTIFP	Motion to Proceed In Forma Pauperis
MTPRO	Motion for Protective Order
MTQSH	Motion to Quash
MTRCS	Motion for Reconsideration
MTRPR	Motion to Redeem Premises
MTREF	Motion to Release Escrow Funds
MTOPT	Motion to Remove Opt-Out of the Proposed Settlement Agreement (Class Action Cases)
MTRWT	Motion to Return Writ of Possession or Execution
MTSAN	Motion for Sanctions
MT229	Motion for Sanctions for Failure to Deliver Settlement Funds
MTSAS	Motion to Set Aside Sheriff's Sale
MTSAA	Motion to Set Aside Award
MTIPP	Motion to Settle Incompetent/ Incapacitated Person's Estate
MTSPR	Motion to Stay Proceedings
MTWOE	Motion to Stay Writ of Execution
MTSTK	Motion to Strike Pleading
MTSJD	Motion for Summary Judgment (30 day hold)
MTRAE	Motion for Supplementary Relief in Aid of Execution
MTRDM	Motion to Reassess Damages
MTREF	Motion for Reimbursement of Fees
MTREL	Motion to Release Bond
MTRDS	Motion to Remove Case from Deferred Status
MTSRC	Motion to Seal Record
MTSEV	Motion to Sever Cases
MTSPP	Motion for Specific Performance
MTTFR	Motion to Transfer
MTTRJ	Motion to Transfer Judgment
MTFTV	Motion for Title to Vehicle
MTWDA	Motion to Withdraw Appearance
MTWPS	Motion for Writ of Possession
MTWRS	Motion for Writ of Seizure
MTMIS	Miscellaneous Motion

CODE	PETITIONS
PTAAR	Petition to Appoint Common Law Arbitrator
PTARC	Petition to Appoint a Receiver
PTCAR	Petition to Compel Arbitration
PTCAW	Petition to Confirm Arbitration Award
PTCST	Petition to Confirm Settlement
PTFCT	Petition for Contempt
PTOJD	Petition to Open Default Judgment
PTSNP	Petition to Open Judgment of Non Pros
PTEMG	Emergency Petition

6. CASE PROGRAM. The party shall check the program to which the case is assigned and provide the requested program data.
7. PARTIES. The filing parties shall set forth the name, address and telephone number of all counsel of record and unrepresented parties, and must attach a stamped addressed envelope for each attorney of record and unrepresented party.
8. OTHER. The parties shall enter other relevant important information in this box – such as request for stay, emergency designation etc. – placing the Motion Clerk on notice of special handling or request.
9. SIGNATURE LINE. The Cover Sheet must be signed, dated and, if applicable, the attorney ID number must be provided.
10. SERVICE. A copy of the file-stamped Petition, Motion, Answer, Response and attachments must be served on all parties of record immediately after filing as required by Pa.R.C.P. 206.6, and Pa.R.C.P. 440.

The Current Version of the Petition/Motion Cover Sheet May Be Downloaded From The First Judicial District's Website: http://courts.phila.gov.

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HERBERT J. NEVYAS, M.D., and	:	COURT OF COMMON PLEAS
ANITA NEVYAS-WALLACE, M.D., and	:	TRIAL DIVISION
NEVYAS EYE ASSOCIATES, P.C.,	:	Philadelphia County
Plaintiffs		NOVEMBER TERM, 2003
	:	NO. 946
vs.	:	
DOMINIC MORGAN, and	:	Control Number **01-09062101**
STEVEN A FRIEDMAN	:	Jury Trial demanded on Counterclaim
Defendants	:	

PROPOSED ORDER

AND NOW, this _____ day of _____, 2009, upon consideration of defendant Friedman's Motion and any responses and/or cross-motions thereto, it is hereby ORDERED that:

1. Plaintiffs are censured for ignoring Judge Sylvester's instructions.

2. Plaintiffs are censured for filing an erroneous federal lawsuit.

3. Plaintiffs are censured for wasting court time, and the claims against defendant Friedman are dismissed.

4. Plaintiffs are censured for wasting court time, and the claims against defendant Friedman are dismissed.

5. Plaintiffs are censured for subverting this court's orders about adding a defendant while restricted to not otherwise amending the complaint**,** and claims that Morgan conspired with Friedman are stricken.

6. The two orders decided while the case was officially in abeyance are rescinded and vacated.

7. Judgment on the Pleadings is granted and the case against defendant Morgan is dismissed.

8. [not applicable]

9. A Compulsory Nonsuit or Judgment of *Non Pros*, and/or Motion for Judgment on the Pleadings; and/or Motion for Summary Judgement to Counts I and II of Plaintiffs' Amended Complaint is granted.

10. A Compulsory Nonsuit or Judgment of *Non Pros*, and/or Motion for Judgment on the Pleadings; and/or Motion for Summary Judgement to Counts I and II of Plaintiffs' Amended Complaint is granted.

11. The defamation suit against Morgan is dismissed.

12. The defamation suit against Morgan is dismissed.

13. The defamation suit against Morgan is dismissed.

14. The Nevyas plaintiffs are at least limited purpose public figures, and acts of negligence alone do not make defendant Morgan liable for defamation.

15. Plaintiffs are censured for swearing falsely, and not producing documents.

16. Plaintiffs are censured for wasting court time.

BY THE COURT

_____

Rogers, J.

Dominic J. Morgan, *pro se*
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HERBERT J. NEVYAS, M.D., and	:	COURT OF COMMON PLEAS
ANITA NEVYAS-WALLACE, M.D., and	:	TRIAL DIVISION
NEVYAS EYE ASSOCIATES, P.C.,	:	Philadelphia County
Plaintiffs		NOVEMBER TERM, 2003
	:	NO. 946
vs.	:	
DOMINIC MORGAN, and	:	Control Number **01-09062101**
STEVEN A FRIEDMAN	:	Jury Trial demanded on Counterclaim
Defendants	:	

***PRO SE* DEFENDANT MORGAN'S RESPONSE TO DEFENDANT FRIEDMAN'S MOTION TO DETERMINE PLAINTIFFS' PUBLIC FIGURE STATUS, AND CROSS MOTIONS FOR COMPULSORY NONSUIT OR JUDGMENT OF *NON PROS*, AND/OR JUDGMENT ON THE PLEADINGS; AND/OR SUMMARY JUDGEMENT TO COUNTS I AND II OF PLAINTIFFS' AMENDED COMPLAINT**.

1. The Nevyas plaintiffs ignored Judge Sylvester's instructions.

   See Section 1 of the Factual and Procedural History in the attached Memorandum.

2. The Nevyas plaintiffs filed an erroneous federal lawsuit.

   See Section 2 of the Factual and Procedural History in the attached Memorandum.

3. The Nevyas plaintiffs failed to properly transfer their federal action back to this court.

   See Section 3 of the Factual and Procedural History in the attached Memorandum.

4. The Nevyas plaintiffs exceeded the one-year statute of limitations against defendant Morgan's *pro bono* attorney.

   See Section 4 of the Factual and Procedural History in the attached Memorandum.

5. The Nevyas plaintiffs improperly claimed that Morgan conspired with Friedman, in their reinstated claim.

   See Section 5 of the Factual and Procedural History in the attached Memorandum.

6. There were motions decided while the case was officially in abeyance.

   See Section 6 of the Factual and Procedural History in the attached Memorandum.

7. There was a motion decided while the case was officially in stay.

See Section 7 of the Factual and Procedural History in the attached Memorandum.

8. The Superior Court's Remand.

See Section 8 of the Factual and Procedural History in the attached Memorandum.

(This quotes from the Superior Court's Remand - there is no question presented and no argument for this section.)

9. The Nevyas plaintiffs fail to allege that defendant Morgan re-posted the same statements that had been on his website as of July 30, 2003.

See Section 9 of the Factual and Procedural History in the attached Memorandum.

10. The Nevyas plaintiffs try to *excuse and exclude* their failure to allege that defendant Morgan re-posted the same statements that had been on his website as of July 30, 2003.

See Section 10 of the Factual and Procedural History in the attached Memorandum.

11. The Nevyas plaintiffs failed to honor their contract with defendant Morgan.

See Section 11 of the Factual and Procedural History in the attached Memorandum.

12. The statements posted on Morgan's website are not defamatory because they are true.

See Section 12 of the Factual and Procedural History in the attached Memorandum.

13. The statements on Morgan's website are either fact or opinion.

See Section 13 of the Factual and Procedural History in the attached Memorandum.

14. The Nevyas plaintiffs are at least limited purpose public figures.

See Section 14 of the Factual and Procedural History in the attached Memorandum.

15. If the Nevyas plaintiffs had not sworn falsely, and had produced the documents they withheld, this instant case would not exist.

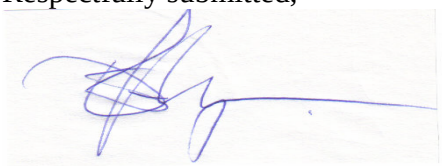
See Section 15 of the Factual and Procedural History in the attached Memorandum.

16. The above are relevant to defendant Morgan's counter-suit.

See Section 16 of the Factual and Procedural History in the attached Memorandum.

WHEREFORE defendant Morgan moves this Honorable Court enter a suitable order granting the Motion of defendant Friedman and the instant Cross Motions of defendant Morgan.

Respectfully submitted,



_____

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HERBERT J. NEVYAS, M.D., and	:	COURT OF COMMON PLEAS
ANITA NEVYAS-WALLACE, M.D., and	:	TRIAL DIVISION
NEVYAS EYE ASSOCIATES, P.C.,	:	Philadelphia County
Plaintiffs		NOVEMBER TERM, 2003
	:	NO. 946
vs.	:	
DOMINIC MORGAN, and	:	Control Number **01-09062101**
STEVEN A FRIEDMAN	:	Jury Trial demanded on Counterclaim
Defendants	:	

***PRO SE* DEFENDANT MORGAN'S MEMORANDUM OF LAW IN RESPONSE TO DEFENDANT FRIEDMAN'S MOTION TO DETERMINE PLAINTIFFS' PUBLIC FIGURE STATUS, AND IN SUPPORT OF HIS CROSS MOTIONS FOR COMPULSORY NONSUIT OR JUDGMENT OF *NON PROS*, AND/OR JUDGMENT ON THE PLEADINGS; AND/OR SUMMARY JUDGEMENT TO COUNTS I AND II OF PLAINTIFFS' AMENDED COMPLAINT**.

I. INTRODUCTION.

Defendant Morgan is sued because plaintiffs are dissatisfied with the content of his website. [1] Morgan created his website to describe his treatment by LASIK eye surgery and to describe his complaints in court and to the FDA (Food and Drug Administration) about his treatment. The website's purpose is to give information to the public, particularly those who may consider having LASIK, from the special perspective of a LASIK casualty - an patient whose life was devastated when surgery worsened his vision.

Law professor James O'Reilly evaluated defendant Morgan's website and wrote a declaration, posted on Morgan's website at <http://www.lasikdecision.com/media2/ordecl.pdf>:

[1] The original <Lasiksucks4u.com> was replaced by <Lasikdecision.com>. The word "website" used here refers to any website owned or operated by Morgan.

2. My professional address is at the College of Law, University of Cincinnati, P.0 210040, Cincinnati, Ohio 45221-0040. I am a member of the Bar of Ohio and Virginia, the Sixth and Federal Circuits and the U.S. Supreme Court. I have taught law students regarding the law of medical devices, products liability and administrative law since 1980, and am the author of more than twenty textbooks and one hundred articles, and have appeared as an FDA law expert in federal and state courts, and have been quoted by the U.S. Supreme Court as an expert on medical device regulation. I understand that the federal regulation of the risks and benefits of medical devices such as LASIK equipment is a matter of substantial public concern and controversy.

3. I published my law review essay, *AN EYE FOR AN EYE: FORESIGHT ON REMEDIES FOR LASIK SURGERY'S PROBLEMS*, at 71 U. Cin. L. Rev. 541 (2002), as part of our Faculty Scholarship symposium issue.

3. I became aware of Mr. Morgan's website, Lasiksucks4u.com, upon the unsolicited recommendation of a person in California who had read my law review article and encouraged me to read Mr. Morgan's website comments. I found the material posted on Lasiksucks4u.com to be educational and useful, particularly for anyone considering having LASIK surgical procedures performed on themselves. I did an internet search using the google.com search engine and believe that the numerical majority of the dozens of sites listed there are commercial vendors of LASIK products or surgeons providing LASIK.

4. After reviewing his site, I corresponded with Mr. Morgan and have encouraged Mr. Morgan to include my essay on his website, in order that persons considering Lasik may become aware of my perspective regarding various legal and regulatory problems involving LASIK surgery. I have provided Mr. Morgan with the electronic version of my essay for posting at his discretion. I have no financial interest in LASIK, have not been paid by Mr. Morgan or others related to LASIK, and had no prior knowledge of Mr. Morgan or of those to whom he makes reference in his website.

5. Although my law review article is legal scholarship directed particularly toward lawyers, I hope its opinions can also be part of the wider education of the public, since I consider public education to be a major responsibility of the legal profession, particularly for legal academics. As a scholar recognized in the field of medical device and products liability law, the general public's awareness of product risks is an extremely important aspect of our protections as members of American society.

6. I believe that Mr. Morgan has an ample First Amendment right to exercise his freedom of speech on matters of public controversy, and to provide the public with information about LASIK, from his personally unique perspective as a victim.

Not only does Morgan’s website have important information, but it links to important

information on other websites, such as Professor O'Reilly's law review essay. [2]

II. FACTUAL AND PROCEDURAL HISTORY, ACCORDING TO TOPIC.

1. The Nevyas plaintiffs ignored Judge Sylvester's instructions.

When commencing their instant lawsuit, plaintiffs separately filed for an emergency preliminary injunction demanding that defendant Morgan's website be shut down. Judge Sylvester ordered a hearing for November 10, 2003 but instead saw the attorneys in chambers and said she wanted to see if a compromise was possible. Judge Sylvester instructed attorney Friedman (not then a defendant) to work with Mr. Morgan on the website; and instructed plaintiffs (who agreed) to afterwards inspect the website and say what, if anything, was still objectionable. Judge Sylvester instructed all *parties*

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[2] Morgan links to professor O'Reilly at <professor-oreilly-speaks-out&catid=19:studies-a-articles&Itemid=192>:

> *I wish to acknowledge with much appreciation for contributing with permission to post on this site by Professor James O'Reilly the following study on Lasik liability exceptions: E-Text Version of article published in 71 Univ. Cincinnati Law Review 541 (2003), copyright Univ. Cincinnati 2003*
> AN EYE FOR AN EYE: FORESIGHT ON REMEDIES FOR LASIK SURGERY'S PROBLEMS Prof. James O'Reilly
> SUMMARY: ... Laser eye surgery is remarkable. ... " The FDA requires device sponsors to report the number of patients who seek a second LASIK procedure to improve vision after the first surgical results were inadequate, but "no laser company has presented enough evidence for the FDA to make conclusions about the safety or effectiveness of enhancement surgery. ... Night vision deficiencies are "one of the main challenges" to improving laser eye surgery. ... The bold and attractive promises being made in LASIK advertising by eye surgery marketing corporations, some of whom are publicly traded entities, may give rise to express warranty claims as well as claims against the individual surgeon or the surgeon's corporate entity as conventional malpractice claims. ... The FDA has jurisdiction over the advertisements for a prescription medical device and, although the FDA requires that warnings be stated for prescription drug ads made to consumers, it does not require the same communication about risks in LASIK advertising. ... The injured LASIK patient's compensation claim against a LASIK device maker is likely to be barred by the Supreme Court's interpretation of the Food Drug & Cosmetic Act to prevent state verdicts asserting design defect claims against FDA- approved medical devices. ..

and counsel come to Court November 17, 2003 for a formal hearing. Attorney Friedman completed his work on November 12, and notified plaintiffs that they should then inspect the website.

On November 17 Mr. Lapat came to court without his clients, said plaintiffs had not inspected the website, and asked for an injunction against the entire website, *claiming there was a contract requiring removal of any mention of Nevyas' name from the website.* Judge Sylvester did not find any such contract, denied the preliminary injunction, and denied reconsideration.

2. The Nevyas plaintiffs filed an erroneous federal lawsuit.

Although defendant Morgan is now *pro se,* he had been defended *pro bono* by defendant Friedman.

Seeking to strip Morgan of Friedman's *pro bono* representation [3], the Nevyas plaintiffs joined Friedman, citing correspondence between Friedman and the FDA which Morgan, and only Morgan, decided to post on his website. Plaintiffs first discontinued this instant lawsuit and then filed a federal lawsuit against both Morgan and Friedman, purporting violation of the Lanham Act and defamation. The Lanham Act is a federal statute barring deceptive use of copyrighted material, and the Nevyas plaintiffs purported that defendant Friedman, an internist, was a competitor of the Nevyases, who are ophthalmologists. The assertions were erroneous and frivolous.

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[3] Not only did Morgan become legally blind after plaintiffs' LASIK, and has severely limited employment, making it impossible for him to pay for legal representation, but plaintiffs opposed Morgan's past motions *in forma pauperis* (not needed at the moment).

Judge Joyner dismissed the complaint 41 days after it was filed. *Nevyas v. Morgan*, 309 F. Supp.2d 673 (E.D. Pa. 2004).

3. The Nevyas plaintiffs failed to properly transfer their federal action back to this court.

Thirteen days after Judge Joyner dismissed the federal complaint, plaintiffs moved to reinstate the instant lawsuit and amend their complaint. Reinstatement was granted. Leave to amend was denied but leave to seek joinder under Rule 2232 was granted.

Three months after dismissal of the federal action, plaintiffs applied under Rule 2232 to join Friedman as a defendant in this case. On July 7, 2004, that motion was granted, and the Amended Complaint naming Friedman was filed on July 13, 2004.

However, plaintiffs did not serve Friedman or file a return of service. On November 19, 2004, plaintiffs did mail a ten-day notice pursuant to Pa. R.C.P. 237.4, notifying Friedman of their intention to take a default. Friedman filed preliminary objections endorsed with a notice to plead, asserting both a failure to effect proper service and a motion to dismiss for failure to state a cause of action. Plaintiffs filed no response to the factual allegations of the preliminary objections but reinstated their amended complaint on January 10, 2005 and served it on Friedman by deputized service on January 13, 2005 *unaccompanied by a transfer of the federal action as is required by section 5103 of the Judicial Code*, 42 Pa. C.S. § 5103(b).

4. The Nevyas plaintiffs exceeded the one-year statute of limitations against defendant Morgan's *pro bono* attorney.

The date on which an item is first "published" on the Internet controls the one-year statute of limitations, and all of Friedman's letters to the FDA were "published" by Morgan *more than one year before* plaintiffs served Friedman on January 13, 2005.

Uniform Single Publication Act, 42 Pa. C.S.A. §§ 8341 et seq.

5. <u>The Nevyas plaintiffs improperly claimed that Morgan conspired with Friedman, in their reinstated claim</u>.

The Nevyas plaintiffs' original complaint was against defendant Morgan only. When the Nevyas plaintiffs received permission to amend their complaint, they were permitted to add defendant Friedman only, and specifically *denied* permission to amend their allegations concerning defendant Morgan.[4]

The Nevyas plaintiffs' *amended* complaint has three (3) counts:

I. Count I is for defamation against defendants Morgan and Friedman, with the restriction that the allegations against Morgan are not amended, only that Friedman is joined.

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[4] Relevant excerpts from the docket indicate those restrictions (highlighting added):
19-MAY-2004 ...
Docket Entry: 55-04032355 AND NOW, THIS 17TH DAY OF MAY, 2004, UPON CONSIDERATION OF PLAINTIFFS DR. HERBERT NEVYAS AND DR. ANITA NEVYAS-WALLACE'S MOTION TO REINSTATE CLAIM AND AMEND COMPLAINT, AND DEFENDANT'S RESPONSE THERETO, IT IS HEREBY ORDERED AND DECREED THAT SAID MOTION IS GRANTED IN PART AND DENIED IN PART AS FOLLOWS: 1. THE REQUEST FOR LEAVE TO REINSTATE IS GRANTED. PLAINTIFFS MUST FORMALLY REINSTATE THEIR COMPLAINT. 2. **THE REQUEST FOR LEAVE TO AMEND IS DENIED. PLAINTIFFS ARE GRANTED LEAVE TO REQUEST RELIEF UNDER PA.R.C.P. 2232. ...**BY THE COURT: CARRAFIELLO, J. 5-17-04

09-JUL-2004 ...
Docket Entry: 87-04060587 AND NOW, THIS 7TH DAY OF JULY, 2004, UPON CONSIDERATION OF **PLAINTIFFS' MOTION FOR RELIEF UNDER RULE 2232(C) TO JOIN ADDITIONAL DEFENDANT, STEVEN FRIEDMAN,** AND DEFENDANT'S RESPONSE THERETO, IT IS HEREBY ORDERED AND DECREED THAT SAID MOTION IS GRANTED. PLAINTIFFS MAY FILE THEIR AMENDED COMPLAINT (ATTACHED TO THE MOTION AS EXHIBIT 3) WITHIN TWENTY (20) DAYS OF THIS ORDER. BY THE COURT: CARRAFIELLO, J. 7/9/04.

For their complaint against Friedman, the Nevyas plaintiffs *invented two entirely new theories.* First, plaintiffs purport that since Friedman gave copies of his attorney letters to the FDA to Morgan and Morgan posted them on his website, Friedman was a publisher of the website. Amended Complaint ¶¶ 73, 83.

The Nevyas plaintiffs' second *invented new theory* is that Morgan and Friedman conspired to defame. Amended Complaint ¶ 82.

This allegation improperly does more than merely join Friedman.

II. Count II is for breach of contract against defendant Morgan only.

III. Count III is for specific performance against defendant Morgan only.

6. There were motions decided while the case was officially in abeyance.

In its March 9, 2007 decision, docketed by the trial court on May 11, 2007, the Superior Court wrote, "On July 26, 2005, the case proceeded to a non-jury trial limited to count III of the second amended complaint, the count for specific performance."

The trial court docket has no mention of the July 26, 2005 trial. Two defense motions submitted *before* trial were decided *after* trial. However, at trial on July 26, Judge Maier orally ordered that *all undecided matters were to be held* ***in abeyance***. Trial transcript p. 95. Thus, two motions were decided while the case was officially in abeyance:

a. Motion for Summary Judgment by defendant Friedman, docket entry 68-05061868, filed June 24, 2005 and *decided after trial and while the case was in abeyance* by Judge Carrafiello on July 29, 2005 and docketed August 2, 2005.

b. Motion for Severance and to Bifurcate by defendant Friedman, docket entry 78-05071578, filed July 21, 2005 and *decided after trial and while the case was in*

abeyance by Judge Glazer on July 29, 2005 and docketed August 15, 2005.

7. <u>There was a motion decided while the case was officially in stay</u>.

The situation with the two motions in the section above is analogous to the Motion for Judgment on the Pleadings by defendant Morgan, docket entry 47-04073347, filed July 9, 2004. That motion was denied during a sixty day stay of all proceedings, but the order was rescinded and vacated September 28, 2004 with a reason given that the order was issued during a stay.

8. <u>The Superior Court's Remand specifies contract terms.</u>

As the Superior Court wrote, "On July 26, 2005, the case proceeded to a non-jury trial limited to count III of the second amended complaint, the count for specific performance." The trial judge's written order was docketed October 19, 2005.

On appeal, the Superior Court both agreed and disagreed with the trial judge, then vacated the trial judge's order and remanded, stating:

> ¶ 30 We agree with the trial court that Morgan agreed to take down the specific libelous wording from his website as posted on July 30, 2003, and that, pursuant to the agreement, those specific libelous statements were to be prohibited thereafter..... Likewise, we find that Morgan did not agree to waive his right to make, if he so chooses and at his own risk, libelous statements in the future, unrelated to the statements on his website as of July 30, 2003.
> ¶ 31 The question remains, however, whether the statements that appeared on the website that are the subject of this action are the same as the prohibited postings of July 30, 2003, and, of course, if not, whether they are in fact defamatory. Accordingly, because these issues were not addressed by the trial court, we vacate the order and remand for further findings and proceedings consistent with this Opinion.

Thus, whereas plaintiffs purported there was a contract requiring defendant Morgan's website not mention the Nevyases name, the Superior Court held there was a

contract requiring *only that defendant Morgan's website not re-post the same statements that had been on his website as of July 30, 2003 if such statements are in fact defamatory.*

9. <u>The Nevyas plaintiffs fail to allege that defendant Morgan re-posted the same statements that had been on his website as of July 30, 2003</u>.

In Count II, plaintiffs repeat their claim before Judge Sylvester, claiming there was a contract requiring removal of any mention of Nevyas' name from the website:

> 95. Plaintiffs and Morgan entered a contract whereby Morgan agreed to remove any and all references to Plaintiffs and their medical practice from the website and Plaintiffs agreed not to file a defamation lawsuit against Morgan.
> Amended Complaint ¶ 95.

However, the Superior Court instead held there was a contract requiring Morgan only to remove and not re-post statements from his website as posted on July 30, 2003 if such statements are in fact defamatory. *See the Superior Court's holdings at ¶¶ 30 and 31 quoted in section 7 immediately above.*

Examination of plaintiffs' amended complaint reveals the indisputable fact that **<u>plaintiffs do NOT allege that any of "the statements that appeared on the website that are the subject of this action are the same as the prohibited postings of July 30, 2003."</u>** Indeed, of twenty (20) website statements which plaintiffs' amended complaint purports to be defamatory, *plaintiffs* specifically note that fourteen (14) are <u>NOT</u> the same because they were either changed or removed. *See* Amended Complaint ¶ 27 (original emphasis removed and boldface added):

27._ Examples of the defamatory statements on the website include:
(a) "I went for my initial consultation at Nevyas Eye Associates in Bala Cynwyd, Pennsylvania. I thought they were reputable. ." **This statement has been changed** and now reads: "I went for my initial consultation at Nevyas Eye Associates in Bala Cynwyd, Pennsylvania. They were advertising extensively (for Lasik . with a laser unapproved by the FDA for commercial use)."
(b) "With all the patients who have been damaged by lasik surgery losing their cases in court is it possible there is a cover-up?" **This statement has since been removed.**

(c) "The performing surgeons overlooked standards of care, their own, as well as federal guidelines, and have advertised extensively for a non-approved device (not allowed)." **This statement has since been removed.**
(d) "Their history to include their investigational device shows at least 11 cases of medical malpractice. From first hand experience with these people, they are not the people they represent themselves to be. They are ruthless, uncaring, and greedy." **This statement has since been removed.**
(e) "They ruined my vision and they ruined my life. They did this to me! I was completely happy prior to and none of this was present prior to the lasik surgery. I trusted these people. They made empty promises to fulfill a now empty life, and I can never forgive nor forget, not that I ever could."
(f) "So again key questions are...Why are the majority of Lasik lawsuits being lost? And, why is nothing done about it? Seems like a cover-up...YES, it really does!" Emphasis in original. **This statement has since been removed.**
(g) "If the procedure is going to be done "experimentally," more than likely the surgeon is using a device not yet approved by the Food and Drug Administration (FDA). Since other devices are already approved, this is rarely to your advantage."
(h) "I was not told that a change in prescription gave me better than the 20/50 Best Corrected Visual Acuity (BCVA) I ever had, and that instead of Lasik, the new prescription would have worked just as well if not better than what I was seeing (refracted to 20/40-2 according to my records)."
(i) "Although the marketing of LASIK focuses on quality of life, informed, consent does not. Instead, the real risks are hidden in medical jargon that never mentions their true effects.
(j) "Is the use of FDA non-approved lasers such as this one an even greater risk to Lasik patients?"
(k) "The following are reports submitted to the FDA by the Nevyas' regarding their **"**black box**"** (laser used for investigational surgery). This is information they do not want the public to know..." **This statement has been changed** and now reads:

"Some of the following reports are submitted to the FDA in 1997 regarding their "black box... Federal law also states: 'A sponsor, investigator or any other person. . . shall not promote or test market an investigational device until FDA has approved the device for commercial distribution.' I could not even begin to tell you how many times I've heard their advertisements on radio stations for Lasik surgery without mention of their laser being part of an investigational study."

(l) "Federal Law requires that every patient who is about to undergo a refractive surgery be given a Patient Information Booklet, published by the manufacturer of the laser used in their surgery. If your surgeon does not give you the patient information booklet, this is a violation of federal law, and your surgeon can be charged with not providing you with full informed consent. Abuse of this FDA mandate is widespread. Most patients have never seen a Patient Information Booklet, because it contains warnings that your surgeon does not want you to see."

(m) "Again, the Nevyas' and their lawyers walk all over the legal system, and seem to be able to do whatever they want, and get away with it.**" This statement has since been removed.**

(n) "I do not understand any of this. I'm the one who has been hurt, and this is for the rest of my life. How is it they walk away only to hurt somebody else?" **This statement has since been removed.**

(o) "I have since been told the end result of the arbitration agreement will not be released (what gives them the right not to abide by arbitration agreement) until I sign a release stating the Nevyas' were not at fault. There is no way I will sign that. They took my sight. They will not take the truth!" **This statement has since been removed.**

(p) "I thought the legal system would see through the tactics these people used, and I see now I was grossly mistaken. There is no justice for the average person, so now I have to make do for myself what the legal system could not do. People need to be informed about these doctors, and I damn well will be telling them." Emphasis in original. **This statement has since been removed.**

(q) "It never really was about the money, it's about how they ruined our lives, and how they walk all over the system, just as they did you." **This statement has since been removed.**

(r) "So, my question is, who's covering up for whom, and why? Why was my case ripped apart so badly in the Philadelphia Court System. . . (Judge Papalini threw out everything that had to do with the device being investigational, and anything to do with the FDA)), then I was told arbitration was the more feasible route to go?" **This statement has since been removed.**

(s) "Their track record is scary in that I found all of this out after my surgeries." **This statement has since been removed.**

(t) "Stupidity or greed on the doctor's part and ignorance on everyone else's, why should I have to suffer living like this?" **This statement has**

since been removed.
Amended Complaint ¶ 27 (original emphasis removed and boldface added).

This failure by plaintiffs to allege in the Amended Complaint that defendant Morgan re-posted the same statements that had been on his website as of July 30, 2003, is repeated throughout the instant case, and plaintiffs' document production is devoid of evidence.

10. The Nevyas plaintiffs try to *exclude* their failure to allege that defendant Morgan re-posted the same statements that had been on his website as of July 30, 2003.

The failure by plaintiffs to allege that defendant Morgan re-posted the same statements that had been on his website as of July 30, 2003, is repeated throughout the instant case.

Plaintiffs have repeatedly tried to confuse the court with regard to this failure, an example being "Plaintiffs' Motion *in Limine* to Exclude Defendants from Offering Evidence Concerning the Content of the Website at Issue due to Defendant Morgan's Destruction of Evidence." In that (not ruled upon) motion plaintiffs, who have the burden of proof, seek to *exclude* the unpleasant (for plaintiffs) fact that they do not allege that any of "the statements that appeared on the website that are the subject of this action are the same as the prohibited postings of July 30, 2003." Plaintiffs show fuzzy logic: they purport defendant Morgan deliberately destroyed his hard-drive to hide the July 30, 2003 website from them; and they purport that they made no copies. Yet plaintiffs obviously saw the website because they quoted it to write their Complaint (*see* Section 9 above).

11. The Nevyas plaintiffs failed to honor their contract with defendant Morgan.

In Count II plaintiffs claim they have a contract with defendant Morgan, such that if

Morgan keeps his part of the contract, then plaintiffs agree not to file a defamation lawsuit:

> 95. Plaintiffs and Morgan entered a contract whereby Morgan agreed to remove any and all references to Plaintiffs and their medical practice from the website and Plaintiffs agreed not to file a defamation lawsuit against Morgan.
>
> Amended Complaint ¶ 95.

The Superior Court held there was a contract, but narrowed Morgan's requirements to only removing and not re-posting statements from his website as posted on July 30, 2003 if such statements are in fact defamatory. *See the Superior Court's holdings at ¶¶ 30 and 31 quoted in section 8 above.*

The Superior Court considered the contract only from the standpoint of Count III, specific performance by Morgan. It did not consider the contract from the standpoint of Count II, breach of contract, and so was silent as to plaintiffs agreeing not to file a defamation lawsuit. Because, as noted in Section 9 above, plaintiffs fail to allege or present evidence in their Amended Complaint (or anywhere) that defendant Morgan re-posted the same statements that had been on his website as of July 30, 2003, plaintiffs have not honored the contract.

12. The statements posted on Morgan's website are not defamatory because they are true.

The Nevyas plaintiffs lied, cheated, concealed, and were dishonest during litigation in at least three cases *(Morgan v. Nevyas et al,* Philadelphia County Court of Common Pleas, April 2000 term, number 2621, *Fiorelli v. Nevyas Eye Associates et al,* Philadelphia County Court of Common Pleas, April 1999 term, number 1174, and *Wills et al v. Nevyas et al,* Philadelphia County Court of Common Pleas, July 2001 term, number 2866).

In those three (3) cases the Nevyases did not produce critical documents by the FDA (Food and Drug Administration) or the Nevyas IRB (Institutional Review Board). For example, in *Morgan v. Nevyas et al* there were over a dozen court orders [5] in 2001 and 2002

[5] Below are excerpts from the docket re those orders:

1. 28-JUN-2001 Docket Entry: ORDERED THAT THE PLAINTIFF'S MOTION TO COMPEL DISCOVERY IS GRANTED. SEE ORDER FOR ADDITIONAL DETAILS. MOSS, J 6/28/01
2. 23-AUG-2001 Docket Entry: ORDERED THAT PLAINTIFFS MOTION TO STRIKE OBJECTIONS AND COMPEL DISCOVERY IS GRANTED. SEE ORDER FOR ADDITIONAL DETAILS. MOSS J. 08 23 01
3. 15-NOV-2001 Docket Entry: ORDERED THAT PLAINTIFFS MOTION TO COMPEL DISCOVERY AND DEPOSITION IS GRANTED. SEE ORDER FOR ADDITIONAL DETAILS. MOSS J. 11 15 01
4. 27-DEC-2001 Docket Entry: ORDERED THAT PLAINTIFFS MOTION TO COMPEL DISCOVERY, DEPOSITION, STRIKE OBJECTIONS AND SANCTIONS IS GRANTED. SEE ORDER FOR ADDITIONAL DETAILS. MOSS J. 12 27 01
5. 04-JAN-2002 Docket Entry: ORDERED THAT DEFENDANTS MOTION FOR A PROTECTIVE ORDER IS DENIED. MOSS J. 12 27 01
6. 14-JUN-2002 Docket Entry: ORDERED THAT THE PLAINTIFF'S MOTION TO STRIKE OBJECTIONS AND COMPEL DISCOVERY IS GRANTED. SEE ORDER FOR TERMS & CONDITIONS. MOSS, J 6/13/02
7. 28-JUN-2001 Docket Entry: ORDERED THAT THE PLAINTIFF'S MOTION TO COMPEL DISCOVERY IS GRANTED. SEE ORDER FOR ADDITIONAL DETAILS. MOSS, J 6/28/01
8. 23-AUG-2001 Docket Entry: ORDERED THAT PLAINTIFFS MOTION TO STRIKE OBJECTIONS AND COMPEL DISCOVERY IS GRANTED. SEE ORDER FOR ADDITIONAL DETAILS. MOSS J. 08 23 01
9. 15-NOV-2001 Docket Entry: ORDERED THAT PLAINTIFFS MOTION TO COMPEL DISCOVERY AND DEPOSITION IS GRANTED. SEE ORDER FOR ADDITIONAL DETAILS. MOSS J. 11 15 01
10. 27-DEC-2001 Docket Entry: ORDERED THAT PLAINTIFFS MOTION TO COMPEL DISCOVERY, DEPOSITION, STRIKE OBJECTIONS AND SANCTIONS IS GRANTED. SEE ORDER FOR ADDITIONAL DETAILS. MOSS J. 12 27 01
11. 04-JAN-2002 Docket Entry: ORDERED THAT DEFENDANTS MOTION FOR A PROTECTIVE ORDER IS DENIED. MOSS J. 12 27 01
12. 14-JUN-2002 Docket Entry: ORDERED THAT THE PLAINTIFF'S MOTION TO STRIKE OBJECTIONS AND COMPEL DISCOVERY IS GRANTED. SEE ORDER FOR TERMS & CONDITIONS. MOSS, J 6/13/02
13. 03-JUL-2002 Docket Entry: ORDERED THAT THE PLAINTIFF'S MOTION TO COMPEL DISCOVERY IS GRANTED. SEE ORDER FOR ADDITIONAL DETAILS. BERNSTEIN, J 7/1/02
14. 08-JUL-2002 Docket Entry: ORDERED THAT THE PLF'S MOTION TO STRIKE OBJECTIONS, COMPEL DISCOVERY AND AWARD SANCTIONS DIRECTED TO DFTS, NEVYAS EYE ASSOC., P.C., & NEVYAS EYE ASSOC OF NEW JERSEY, P.C., IS GRANTED. SEE ORDER FOR TERMS & CONDITIONS. BERNSTEIN, J 7/8/02

that such documents be produced. In defiance of those orders, the Nevyases produced sworn affidavits that the particular documents did not exist. Then, on April 29, 2005; May 5, 2005; and May 6, 2005, during discover in the instant case, the Nevyases allowed attorneys Albert and Friedman to come to their medical offices to examine documents.

This document production was in contrast to *Morgan v. Nevyas et al*, where documents could only be seen in the Nevyases' attorneys office, were Bates numbered in advance (1 to 257; 558 to 583; and 613 to 1760), and the Nevyases attorney was present. For document production in the instant case, the Nevyases' secretaries produced unnumbered documents and the Nevyases' attorney was not present throughout.

As attorneys Albert and Friedman examined the documents, they realized the unnumbered documents included documents that the Nevyases previously had sworn *(in Morgan v. Nevyas et al)* did not exist. In all, some 3500 pages had not been produced in *Morgan v. Nevyas et al.* Attorneys Albert and Friedman asked that all the documents be numbered. Of the 3500 pages, the following were materially significant to the *Morgan v. Nevyas et al* case - *they would have made a difference in how that case was handled and its outcome* - and are attached as Exhibits A, B, and C (all handwriting on various pages was made by the Nevyases):

A. April 29, 2005 - Bates numbered FDA-2 to FDA-10; FDA-13 to FDA-60; FDA-66 to FDA-78; FDA-83; and FDA-167 to FDA-170.

B. May 5, 2005 - Bates numbered 1 to 27; 34 to 91; 94 to 96; and 100 to 121.

C. May 6, 2005 - Bates numbered NYA 4; NYA 49; NYA 74 to NYA 75; NYA 120 to NYA 148; NYA 223 to NYA 230; NYA 357 to NYA 371; NYA 511; NYA 667 to NYA 680; NYA 690 to NYA 694; NYA 717; NYA 733 to NYA 736; NYA 758; NYA 785 to NYA 787; NYA 807 to NYA 808; NYA 872 to NYA 877; NYA 922; NYA 939 to NYA 941; NYA 1355 to NYA 1356; NYA 1448 to NYA 1451; NYA 1036 to NYA 1938; NYA 2144 to NYA 2146; and NYA 2266 to NYA 2267.

The documents in Exhibits A, B, and C show that the Nevyases were repeatedly warned

about violation of federal law and/or regulation and/or protocol, and repeatedly avoided compliance. Example are:

A) letter from FDA May 8, 1997

> Because your excimer laser system, which you have told us is being used to treat patients, has neither an approved application for premarket approval (PMA) under section 515(a) of the Federal Food, Drug and Cosmetic Act (the Act), nor an IDE under section 520(g), your device is adulterated under section 501 (f)(1)(B). This is to advise you that consequently, any use of these devices to treat patients is a violation of the law."
> Exhibit A at p. 4.

B) letter from FDA July 29, 1997

> 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. 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.
> Exhibit A at p. 13-15.

C) letter from FDA January 7, 1999

> During the period of October 6, 1998, Nevyas Eye Associates was visited by Mr. Ronald Stokes, an investigator from the Food and Drug Administration's (FDA) Philadelphia District Office....Our review of the inspection report submitted by the district revealed deviations from Title 21, Code of Federal Regulations, (21 CFR), Part 812 - Investigational Device Exemptions and Part 50 - Protection of Human Subjects and Section 520(g) of the Act.
> Exhibit A at p. 49.

D) letter from FDA January 7, 1999

> 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.
> Exhibit A at p. 50. [1]

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[1] This withheld letter and the below memo dated April 19, 2005 from Dr. Sterling, Nevyas' employee, to Mr. Silverman, Nevyas' attorney, provide information that would have been materially significant in the *Wills et al v. Nevyas et al* case, and which the Nevyases denied:

> Mr. Silverman: Last week Dr. Nevyas requested some information regarding the Summitt Excimer laser that we used to in the Marlton, NJ office. That laser was used for hyperopes (far sightedness) and for a few custom ablation procedures and enhancements.

E) letter from FDA January 7, 1999

> During the inspection, Mr. Stokes also discussed with you the need to have advertisements related to your IDE study approved by the reviewing IRB. A transcript of a radio advertisement that had aired for several weeks was included with the inspection report (copy enclosed)....the enclosed advertisement would not be appropriate for soliciting subjects for your IDE study.
> Exhibit A at p. 51.

F) letter from FDA February 6, 2002

One case that was done on 8-19-98 was Keith Wills on his right eye and then Mr. Wills left eye on 2-24-99 and his right eye again on 2-24-99. The last case done with the Summitt laser was 2-10-00 and the 1st case was 3-25-91.
Richard Sterling
Exhibit A at p. 27.

> Please address the following questions and concerns with regard to this submission, which also applies to the previous, delinquent , annual report as outlined in FDA's letter of April 10, 2000, and for which we never received a response....If you do not provide this information within 45 days from the date of this letter, we may take steps to propose withdrawal of approval of your IDE application.
> Exhibit A at p. 167-170.

Certain of the documents in Exhibits A, B, and C, cited below, show that the Nevyases lied, cheated, concealed, and were dishonest about ordered production insofar as:

1. their new centration technique. See exhibit A at pages FDA-59.
2. a report by Herbert Nevyas' brother-in-law, Dr. Barrett, admitting that permanent vision loss from Lasik suction rings occurred in patients other than Morgan, when the Nevyases testified that such was impossible to occur. See exhibit B at page 113.
3. a listing of 30 patients whose vision was damaged by Nevyases' Lasik. See Exhibit C at pages NYA 138 through 147.
4. documents showing that Nevyases were telling their own Institutional Review Board (IRB) that they had no serious adverse events or complaints from doing Lasik. *See*, for example, exhibit C at page NYA 1937.

In addition to showing that that the Nevyases lied, cheated, concealed, and were dishonest about ordered production, a partial listing of documents also showing that according to the FDA:

5. the Nevyases violated federal law when they used their Lasik device before August 7, 1997, such as operating upon Cheryl Fiorelli March 20, 1997; May 15, 1997, and

July 10, 1997. See exhibit A at pages FDA-4, 6, 13, and 14. [2]

6. the Nevyases violated federal law when they promoted and commercialized their Lasik device. See exhibit A at pages FDA-15 and 51.

7. the Nevyases violated federal law when they re-treated various patients, particularly in their New Jersey facility. See exhibit A at pages FDA- 40, 42, 50, and 52.

8. the Nevyases violated federal law when they did not protect human subjects. See exhibit A at pages FDA-49.

9. the Nevyases violated FDA regulations, and were delinquent reporting to the FDA.. See exhibit A at pages FDA-167, 168, and 169.

10. the Nevyases were repeatedly warned of these violations. For example, see exhibit A at pages 19, 20, and 21.

[2] Indeed, the Nevyases trumpet their violation of federal regulation on their own website. Although the Nevyases did not seek permission from the FDA for doing experimental LASIK until March 18, 1997, they blatantly write, "The excimer laser was first approved [for other doctors] for use on the cornea in 1995; we began performing LASIK at that time...." See last paragraph of <http://www.nevyas.com/lasik.html>.

Those who violate federal law and FDA regulations, defy court orders, swear false affidavits, fail to protect human subjects, and are delinquent in reporting to the FDA, are criminals, even if not convicted. Their criminal activity leads them to lie, conceal truth, and not be reputable, honest, or caring. They make empty promises, and are deceitful, ruthless, greedy, not trustworthy, and not the people they represent themselves to be. They are disgraces to their profession, manipulate or walk over the legal system, and sometimes seem to be able to do whatever they want and get away with it. They try to cover up their illegal activities, cause suffering, and ruin lives. This is stupid, because honesty is the best policy.

13. The statements on Morgan's website are either fact or opinion

Defendant Morgan's opinion is that all the statements posted on his website are either factually true or things he believes to be factually true, even if the Nevyases do not consider them proven true.

14. The Nevyas plaintiffs are at least limited purpose public figures

Defendant Morgan incorporates here the Motion of defendant Friedman, concerning the limited public figure status of the Nevyas plaintiffs, *and adds to it:*

The Nevyas plaintiffs are at least limited purpose public figures as defined by the Electronic Frontier Foundation: "A limited-purpose public figure is one who (a) voluntarily participates in a discussion about a public controversy, and (b) has access to the media to get his or her own view across." <http://www.eff.org/issues/bloggers/legal/liability/defamation>

Here the public controversy concerns medical care and doctors, and/or eye care and eye doctors, both ongoing topics in American society, and includes:

(1) what is vision enhancement, who may be candidates?;

(2) what is LASIK, and what are its indications, contraindications, risks, and alternatives such as PRK ?;

(3) why are one-third of LASIK patients (more than two million) not satisfied with LASIK results, according to a survey reported October 14, 2005 in Refractive Surgery News?

(4) what is a “doctors’ doctor,” and how can the Nevyases claim they are?

(5) do doctors pay kickbacks to get patients referred for LASIK?

(6) how and why is the civil justice system inadequate to handle doctors who abuse the system?;

(7) how and why do doctors avoid FDA regulation, and why does the FDA have to protect the public, especially from doctors avoiding regulation?

(8) is the general public's awareness of product risks is an extremely important aspect of our protections as members of American society?

(9) does the public have a right to patient examples of FDA failure to protect citizens from improper surgery, especially LASIK?

(10) what a doctor tells the public that his medical device is *approved* by the FDA and it is *approved* by the FDA only for experimental testing, is that the same?

(11) if one were to have LASIK, is a unit which was never approved for the FDA (except for experimental use) better than devices which have full FDA approval?

(12) when a citizen loses a lawsuit, does he have the right to discuss his loss?

(13) when the majority of websites discussing LASIK are commercial vendors of LASIK products or surgeons providing LASIK, shouldn’t a patient’s website be welcomed for its different perspective?

(14) if one were to have LASIK, how can one decide which doctor or which device?

(15) why do entertainment and sports figures have LASIK when some of them are damaged, such as Jermaine Dupri ("Grammy winning songwriter goes blind") and Kenny Perry ("golfer withdraws from PGA championship")?

(16) when a doctor advertises for patients, doesn't public interest entitle the public to hear from former patients, particularly if they have cautionary roles?

The Nevyas plaintiffs use the media to offer their opinions to the public on a variety of issues, including the topics listed above, and have invited public opinion.[3] Such use of media includes:

(1) advertising their practice and LASIK on KYW radio - those advertisements induced Morgan to have LASIK by the Nevyases;

(2) advertising their practice and LASIK on cable television, using a half-hour long "informational" paid for by Nevyas and prepared by MD-TV;

(3) advertising their practice and LASIK in assorted magazines, such as Philadelphia Magazine's annual doctor issue;

(4) advertising their practice and LASIK in the "Find a Qualified Eye Surgeon for Corrective Eye Surgery" section of Staar Surgical: On the Forefront of Refractive

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[3] Examples of the Nevyases using media for opinions on non-medical topics over the years are:

a. war: July 22, 2003 at <http://www.danielpipes.org/1169/lee-harris-on-why-the-us-is-discarding-wars-rules>

b. academic protesting: Dec 1, 2004 at <http://www.danielpipes.org/2255/hamid-dabashi-columbia-universitys-hysterical-professorDabashi doeth protest too much >

c. Iraq: Dec 19, 2006 at http://www.danielpipes.org/715/uprising-crips-and-bloods-tell-the-story-of-americas-youth>

d. gambling: September 20, 2008 at <http://bits.blogs.nytimes.com/2008/04/01/congress-to-take-testimony-on-internet-gambling>

Technology at <http://www.staar.com/html/find-eye-surgeon.php?state=nj>.

(5) photo and text feature about Nevyas eye surgery in The Pennsylvania Gazette, Jan-Feb 2006, both in print and on the internet: *Envisioning Sight: Anita Nevyas-Wallace helps other see.* The internet version is at <http://www.upenn.edu/gazette/0306/pro03.html>.(6) front-page photo and text feature about Nevyas eye surgery in The Philadelphia Inquirer, Sunday Neighbors Section, October 30, 2005 (section L, page 1): *Vision Accomplished - A new way to look at things*.

Readers were invited to "Share your thoughts at http://go.philly.com/mltalk," where their opinions were posted on the internet;

(7) contributing to various public interest websites such as Quackwatch, an internet website that purports to expose doctor misconduct, examples being *Your Guide to Refractive Surgery* at <http://www.quackwatch.org/03HealthPromotion/rk.html> and *A Message to Glaucoma Patients: Don't Waste Money on Overpriced Eyedrops* at <http://www.quackwatch.org/04ConsumerEducation/glaucomadrops.html>. Quackwatch is managed by Herbert Nevyas' brother-in-law, Dr. Stephen Barrett, and although Quackwatch may seem to get involved with almost every case of doctor misconduct, it avoids discussing the Nevyases and hosts their communications to the public;

(8) advertising their practice and LASIK on internet websites. Searching the internet for "Nevyas eye care" or "Nevyas in the news" or similar topics by search engines such as Google shows that most "hits" are for sites sponsored by Nevyas or his brother-in-law Dr. Barrett.

(9) On one website owned and managed by the Nevyases,

<http://www.nevyas.com/in_the_news.html>, they provide a partial listing of being in the news, citing various newspaper and magazine stories about Nevyas eye surgery from *The Philadelphia Inquirer; The Trend; The City Suburban News-Philadelphia & Main Line; The Trevose PA Weekly*; and news releases by Nevyas Eye Associates. The articles are entitled:

a. Cataract Surgery: A Crystal Clear Decision

b. Exciting New Advancements for Highly Nearsighted People

c. Area Doctor Saves Sight and Learns Unexpected Lessons in Rural Mexico

d. A New Way to Look at Things

e. Northeast Philadelphia Woman's Sight Restored with New Implantable Lens

f .Local Surgeon Travels to Mexico

g. Local Army National Guard Staff Sgt. is granted his wish of LASIK surgery

(10) Indeed, the Nevyas plaintiffs have announced that they have a new website "under construction" about their practice and LASIK, and that it will feature *video* about their practice and LASIK. *See* <http://www.nevyasvideo.com/>.

15. If the Nevyas plaintiffs had not sworn falsely, and had produced the documents they withheld, this instant case would not exist.

If the Nevyas plaintiffs had not sworn falsely, and had produced the withheld documents discussed in section 12 above, this instant case would not exist. The *Wills et al v. Nevyas et al, Fiorelli v. Nevyas Eye Associates et al*, and *Morgan v. Nevyas et al* cases would have been handled differently with probably different results, and the FDA would probably have done more than merely terminate the Nevyas' IDE (Investigational Device Exemption) "for reasons of public safety."

16. The above are relevant to defendant Morgan's counter-suit

Defendant Morgan incorporates all of the above into his countersuit, which is rooted in the Nevyas plaintiffs threatening and intimidating Morgan's internet carriers, and misrepresenting court orders to them, causing them to shut Mr. Morgan's website.

If the Nevyas plaintiffs had not sworn falsely, and had produced the withheld documents discussed in sections 12 and 15 above, this instant case and the countersuit would not exist.

III. QUESTIONS PRESENTED, LISTED ACCORDING TO TOPIC IN FACTUAL AND PROCEDURAL HISTORY ABOVE:

1. Did the Nevyas plaintiffs ignore Judge Sylvester's instructions?

   Suggested answer: Yes.

2. Did the Nevyas plaintiffs file an erroneous federal lawsuit?

   Suggested answer: Yes.

3. Did the Nevyas plaintiffs fail to properly transfer their federal action back to this court?

   Suggested answer: Yes.

4. Did the Nevyas plaintiffs exceed the one-year statute of limitations against defendant Morgan's *pro bono* attorney?

   Suggested answer: Yes.

5. Did the Nevyas plaintiffs improperly claim that Morgan conspired with Friedman, in their reinstated claim?

   Suggested answer: Yes.

6. Were motions decided while the case was officially in abeyance?

   Suggested answer: Yes.

7. Was a motion decided while the case was officially in stay?

Suggested answer: Yes.

8. The Superior Court's Remand - *no question presented*.

9. Did the Nevyas plaintiffs fail to allege that defendant Morgan re-posted the same statements that had been on his website as of July 30, 2003?

Suggested answer: Yes.

10. Did the Nevyas plaintiffs try to *excuse and exclude* their failure to allege that defendant Morgan re-posted the same statements that had been on his website as of July 30, 2003?

Suggested answer: Yes.

11. Did the Nevyas plaintiffs fail to honor their contract with defendant Morgan?

Suggested answer: Yes.

12. Are the statements posted on Morgan's website are not defamatory because they are true?

Suggested answer: Yes.

13. Are the statements on Morgan's website either fact or opinion?

Suggested answer: Yes.

14. Are the Nevyas plaintiffs at least limited purpose public figures?

Suggested answer: Yes.

15. If the Nevyas plaintiffs had not sworn falsely, and had produced the documents they withheld, would this instant case exist?

Suggested answer: NO.

16. Are the above relevant to defendant Morgan's counter-suit?

Suggested answer: Yes.

IV. ARGUMENT, LISTED ACCORDING TO TOPIC IN FACTUAL AND PROCEDURAL HISTORY, AND QUESTIONS PRESENTED ABOVE:

1. The Nevyas plaintiffs ignored Judge Sylvester's instructions.

Section 1 of the above Factual and Procedural History is incorporated here.

Plaintiffs failed to keep their word with Judge Sylvester.

WHEREFORE, in light the time this court and the Superior Court consequently wasted, plaintiffs deserve censure.

2. The Nevyas plaintiffs filed an erroneous federal lawsuit.

Section 2 of the above Factual and Procedural History is incorporated here.

WHEREFORE, in light the time this court and the Superior Court consequently wasted, plaintiffs deserve censure.

3. The Nevyas plaintiffs failed to properly transfer their federal action back to this court.

Section 3 of the above Factual and Procedural History is incorporated here.

The Nevyas plaintiffs were required to transfer their federal action back to this court. 42 Pa. C.S.A. § 5103(a) & (b) (1 & (2), Transfer of Erroneously Filed Matters provides:

> (a) General rule. – If an appeal or other matter is taken to or brought in a court or magisterial district of this Commonwealth which does not have jurisdiction of the appeal or other matter, the court or district justice shall not quash such appeal or dismiss the matter, but shall transfer the record thereof to the proper tribunal of this Commonwealth, where the appeal or other matter shall be treated as if originally filed in the transferee tribunal on the date when the appeal or other matter was first filed in a court of magisterial district of this Commonwealth. A matter which is within the exclusive jurisdiction of a court or district justice of this Commonwealth but which is commenced in any other tribunal of this Commonwealth shall be transferred by the other tribunal to the proper court or magisterial district of this Commonwealth where is shall be treated as if originally filed in the transferee court or magisterial district of this Commonwealth on the date when first filed in the other tribunal.
> (b) Federal cases. –
> (1) Subsection (a) shall also apply to any matter transferred or remanded by

> any United States court for a district embracing any part of this Commonwealth. In order to preserved a claim under Chapter 55 (relating to limitation of time), a litigant who timely commences an action or proceeding in any Untied States court for a district embracing any part of this Commonwealth is not required to commence a protective action in a court or before a district justice of this Commonwealth. Where a matter is filed in any United States court for a district embracing any part of this Commonwealth and the matter is dismissed by the United States court for lack of jurisdiction, any litigant in the matter filed may transfer the matter to a court or magisterial district of this Commonwealth by complying with the transfer provisions set forth in paragraph (s).
> (2) Except as otherwise prescribed by general rules, or by order of the United States court, such transfer may be effected by filing a certified transcript of the final judgment of the Untied States court and the related pleadings in a court or magisterial district of this Commonwealth. The pleadings shall have the same effect as under the practice in the United States court, but the transferee court or district justice may require that they be amended to conform to practice in this Commonwealth. Section 5535(a)(2)(i) (relating to termination of prior matter) shall not be applicable to a matter transferred under this subsection.

Plaintiffs have not effected a transfer. In order for an action erroneously filed in federal court to be refiled in state court, it is required that the unsuccessful plaintiffs promptly transfer the action to state court, strictly following the procedures specified by Section 5103(b) of the Judicial Code, 42 Pa. C.S. § 5103(b).

There was no such action taken here, and the service upon defendant Friedman were not preceded by any such transfer. Kurz v. Lockhart, 656 A.2d 160 (Pa. Cmwth. 1995) (delay in transfer barred plaintiff's action), appeal denied, 544 Pa. 649, 664 A.2d 977 (1995). Even partial compliance with the requirements of section 5103(b) will not suffice to permit a plaintiff whose federal court action was pursued without federal jurisdiction to file a subsequent state court action. Collins v. Greene County Mem. Hosp., 419 Pa. Super. 519, 615 A.2d 760 (1992), aff'd, 536 Pa. 475, 640 A.2d 379 (1994), cert. denied, 513 U.S. 943 (1994); Maxwell Downs, Inc. v. Philadelphia, 638 A.2d 473 (Pa. Cmwth. 1994).

Thus, in Kelly v. Hazleton Gen. Hosp., 837 A.2d 490 (Pa. Super. 2003) the Superior Court held that, even thought the plaintiff there had filed a complaint in state court within sixteen days of dismissal of the federal court action, the fact that praecipe to transmit federal court order and opinion to the Common Pleas Court did not occur until eight months after dismissal was fatal to further prosecution of plaintiff's claim. Kelly, supra. Therefore, absent effective timely service upon Friedman following transfer, plaintiffs' Amended Complaint is "dead" as to him. *See* Township of Lycoming v. Shannon, 780 A.2d 835 (Pa. Cmwlth. 2001). The required service of amended complaints upon new parties provides no exception to this statutory requirement. *See* City of Philadelphia v. Berman, 863 A.2d 156, 160 n.9 (Pa. Cmwlth. 2004).

As the Superior Court held in Kelly, any assertion by plaintiffs of their good faith or alleged lack of prejudice to defendant Friedman is also immaterial. *See also* Teamann v. Zafris, 811 A.2d 52 (Pa. Cmwlth. 2002), appeals denied sub nom. Baker v. Zafris, 574 Pa. 755, 830 A.2d 976, and 574 Pa. 761, 831 A.2d 600 (Pa. 2003); Beglin v. Stratton, 816 A.2d 370 (Pa. Cmwlth. 2003).

WHEREFORE, the claims against defendant Friedman should be dismissed and, in light the time this court and the Superior Court consequently wasted, plaintiffs deserve censure.

4. The Nevyas plaintiffs exceeded the one-year statute of limitations against defendant Morgan's *pro bono* attorney.

Section 3 and 4 of the above Factual and Procedural History are incorporated here, as is Argument Section 3 immediately above.

WHEREFORE, the claims against defendant Friedman should be dismissed and, in

light the time this court and the Superior Court consequently wasted, plaintiffs deserve censure.

5. The Nevyas plaintiffs improperly claimed that Morgan conspired with Friedman, in their reinstated claim.

Section 5 of the above Factual and Procedural History is incorporated here.

WHEREFORE, the claim that Morgan conspired with Friedman should be stricken, and plaintiffs deserve censure for subverting this court's orders about adding a defendant while restricted to not otherwise amending the complaint**.**

6. There were motions decided while the case was officially in abeyance.

Section 6 of the above Factual and Procedural History is incorporated here.

WHEREFORE, the two orders concerning the two motions decided while the case was officially in abeyance should be rescinded and vacated.

7. There was a motion decided while the case was officially in stay.

Section 7 of the above Factual and Procedural History is incorporated here.

WHEREFORE, Judgment on the Pleadings should be granted and the case against defendant Morgan dismissed.

8. The Superior Court's Remand.

Section 8 of the above Factual and Procedural History is incorporated here.

This quotes from the Superior Court's Remand - there is *no question presented* and no argument for this section.

9. The Nevyas plaintiffs fail to allege that defendant Morgan re-posted the same statements that had been on his website as of July 30, 2003.

Section 9 of the above Factual and Procedural History is incorporated here

WHEREFORE, a Compulsory Nonsuit or Judgment of *Non Pros*, and/or Motion for Judgment on the Pleadings; and/or Motion for Summary Judgement to Counts I and II of Plaintiffs' Amended Complaint should be granted.

10. The Nevyas plaintiffs try to *excuse and exclude* their failure to allege that defendant Morgan re-posted the same statements that had been on his website as of July 30, 2003.

Section 10 of the above Factual and Procedural History is incorporated here.

WHEREFORE, a Compulsory Nonsuit or Judgment of *Non Pros*, and/or Motion for Judgment on the Pleadings; and/or Motion for Summary Judgement to Counts I and II of Plaintiffs' Amended Complaint should be granted.

11. The Nevyas plaintiffs failed to honor their contract with defendant Morgan.

Section 11 of the above Factual and Procedural History is incorporated here.

WHEREFORE, the contract should be enforced and the defamation suit against Morgan dismissed.

12. The statements posted on Morgan's website are not defamatory because they are true.

Section 12 of the above Factual and Procedural History is incorporated here.

WHEREFORE, the contract should be enforced and the defamation suit against Morgan dismissed.

13. The statements on Morgan's website are either fact or opinion.

Section 13 of above Factual and Procedural History is incorporated here.

Both facts and opinion are protected free speech under the US and Pennsylvania constitutions.

WHEREFORE, the contract should be enforced and the defamation suit against

Morgan dismissed.

14. The Nevyas plaintiffs are at least limited purpose public figures.

Section 14 of above Factual and Procedural History is incorporated here.

Defendant Morgan also incorporates here the Motion of defendant Friedman, concerning the limited public figure status of the Nevyas plaintiffs.

WHEREFORE, acts of negligence alone should not make defendant Morgan liable for defamation.

15. If the Nevyas plaintiffs had not sworn falsely, and had produced the documents they withheld, this instant case would not exist.

Section 15 of above Factual and Procedural History is incorporated here.

WHEREFORE, in light the time this court and the Superior Court consequently wasted, plaintiffs deserve censure.

16. The above are relevant to defendant Morgan's counter-suit.

Section 16 of above Factual and Procedural History is incorporated here.

WHEREFORE, in light the time this court and the Superior Court consequently wasted, plaintiffs deserve censure.

Wherefore, **defendant Morgan asks this honorable Court to enter appropriate Orders, per the suggested Order attached.**

V. CONCLUSION:

Inasmuch as plaintiffs' claims are totally without foundation, defendant Morgan asks that this Court enter judgment in his favor per the suggested Order attached.

VI. VERIFICATION:

I, Dominic J. Morgan, defendant *pro se* verify these statements to be true, and understand that these statements are made subject to penalties of 18 Pa.C.S. Sec. 4904 relating to unsworn falsification to authorities.

VII. CERTIFICATE OF SERVICE:

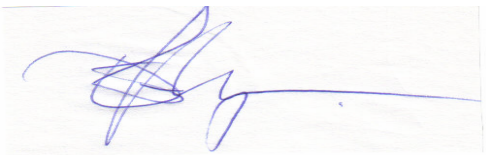
I certify that a true and correct copy of the attached document has been e-mailed or mailed first class prepaid to the persons listed below on the date listed below:

Leon Silverman, Esquire
Stein & Silverman, P.C.
230 South Broad Street, 18TH Floor
Philadelphia, PA. 19102
215-985-0822

Maureen Fitzgerald, Esquire
Eckert Seamans Cherin & Mellott, LLC
2 Liberty Place
50 South 16th Street - 22nd Floor
Philadelphia, PA 19102
mfitzgerald@eckertseamans.com

215-851-8400

Respectfully submitted,



Dated July 8, 2009

_____
Dominic J. Morgan, *pro se*

Exhibit A

APR 14 1997

DEPARTMENT OF HEALTH AND HUMAN SERVICES — Public Health Service

Food and Drug Administration
Center for Devices and
Radiological Health
9200 Corporate Blvd.
Rockville, Maryland 20850

APRIL 09, 1997

HERBERT J. NEVYAS, M.D.
DELAWARE VALLEY LASER SURGERY INSTITUTE
TWO BALA PLAZA
333 EAST CITY AVENUE
BALA CYNWYD, PA 19004
ATTN: HERBERT J. NEVYAS, M.D.

Dear Sponsor:

The information you have submitted, as required by the Food and Drug Administration (FDA) investigational device exemptions (IDE) regulation, has been assigned the following document control number:

IDE Number: G970088
Dated: 18-MAR-97
Received: 08-APR-97
Device: NEVYAS EXCIMER LASER SYSTEM

FDA will notify you when the review of this submission has been completed or if any additional information is required. In accordance with Section 812.30 of the IDE regulation, you may begin your investigation 30 days after the date FDA received your submission, unless FDA notifies you that your investigation may not begin.

Any questions concerning this submission should be directed to the undersigned at (301) 594-2205. Any future correspondence regarding this submission should be identified with your IDE number and should be submitted, in triplicate, to :

Food and Drug Administration
Center for Devices and
Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, Maryland 20850

Sincerely,

FDA 0 0002

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

C D R H
Division of Ophthalmic Devices

9200 Corporate Boulevard
Rockville, MD 20850
FAX NO. 301 480-4201

Date: May 8, 1997 Time: 3:45 P EDT

To: Christine Lodney FAX #: 610-668-1509

Organization: Delaware Valley Laser Surgery Institute

From: Everette T. Beers

Department: Diagnostic & Surgical Devices

Subject: Disapproval of IDE

No. of Pages: 10
(Including Cover Sheet)

Comments:

☐ As Requested ☐ FYI ☐ Read and Destroy

☐ Response Needed ☐ Signature ☐ Circulate

☐ For Correction ☐ Investigate ☐ File

Division Director	301 594-2205
Diagnostic and Surgical Devices Branch	301 594-2018
Vitreoretinal and Extraocular Devices Branch	301 594-1744
Intraocular and Corneal Implants Branch	301 594-2053
Mail Code: HFZ 460	

FDA 0 0003

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 8 1997

Herbert J. Nevyas, M.D.
Nevyas Eye Associates
Delaware Valley Laser Surgery Institute
333 City Line Avenue
Bala Cynwyd, PA 19004

Re: G970088
Sullivan Excimer Laser System (Nevyas Model)
Indications for Use: LASIK for Myopia (-0.5 to -22 Diopters with up to -7 D Astigmatism)
Dated: March 18, 1997
Received: April 8, 1997

Dear Dr. Nevyas:

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. Because your excimer laser system, which you have told us is being used to treat patients, has neither an approved application for premarket approval (PMA) under section 515(a) of the Federal Food, Drug and Cosmetic Act (the Act), nor an IDE under section 520(g), your device is adulterated under section 501(f)(1)(B). This is to advise you that, consequently, any use of these devices to treat patients is a violation of the law.

Our disapproval of your IDE is based on the following deficiencies:

1. On page 22 you indicate that cadaver eyes were ablated with the laser and topography measurements were taken to verify uniformity of ablation. Since your submission contains no actual ablation profiles (other than the theoretical ablation patterns in Attachment 3.4.1.3.A-1) which show that the laser can actually function as designed, please provide the corneal topographies of the cadaver eyes, or provide corneal topographies from your previous clinical studies.

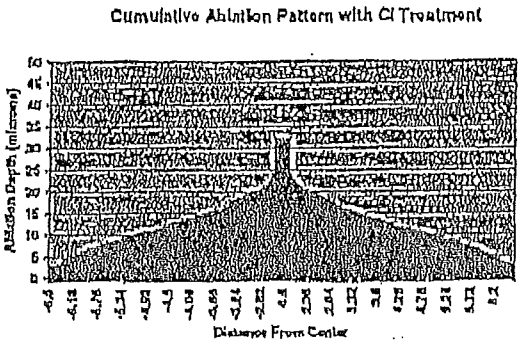
2. You have not provided a sufficiently detailed scientific and technical analysis of the following critical engineering aspects of your device. Please provide this information for each refractive indication being studied:

FDA 0 0034

a. Please provide a description of the pattern of ablation including detailed diagrams and explanations of the hardware and software components involved in generating the new surface (variable apertures, masks, annulae, crescents, diaphragms, multizones, multipasses, and scanning patterns).

b. Please provide cross-sectional views (profilometry) of the PMMA ablation for each indication (minimum and maximum), including astigmatism, and compare the theoretical versus the actual (achieved) plot. This profilometry should be for your particular device, rather than for a generic or similar laser. In addition, please provide the following information on your profilometry measurement: signal to noise ratio, accuracy of depth measurement, accuracy of transverse movement, and number of measurement points per surface.

c. The pattern depicted below is from page 153 of your submission and shows theoretically the cumulative effect of a -3.0 diopter ablation using your multizone, multipass ablation algorithm.



As seen in the diagram, it appears that the central 2 mm of the ablation is flat (uncorrected), with steep slope (approximately infinite) for about 25% of the ablation depth (8 microns out of 32 microns), then continuing with more modest slope out to 6.6 mm. Please explain:

i. During vision with narrowed pupils at 2 mm diameter, is the refraction of the cornea the same as prior to surgery (since that area did not receive a modification of the curvature)?

ii. During vision with pupils greater than 2 mm diameter, will glare and halo be significantly increased?

iii. Please relate this theoretical pattern to your profilometry measurements and explain any differences.

iv. Please provide scientific documentation that a final aperture opening of 2 mm does not adversely affect the quality of the ablation profile and whether or not it could induce complications.

d. Please provide the etch rate and the precision of the etch rate for your laser.

e. The Spiricon beam analysis provided in Attachment 2.1.B-1 does not appear to be from your laser but, possibly, from a laser similar to yours. Please provide one of the following: (1) a detailed Spiricon beam analysis from your laser; (2) certification from Spiricon that the data presented are from your laser; (3) some other measurement of beam homogeneity performed on your laser; or, (4) appropriate manufacturing information demonstrating that your device is the same (in terms of all components comprising the laser and optics generating the beam, method of manufacture, and GMP compliance) as the device measured in the Spiricon beam analysis. The beam homogeneity measurements should be performed on the beam at the treatment plane at maximum diaphragm opening.

f. Please provide additional details regarding methods for obtaining and maintaining both temporal and spatial beam homogeneity.

g. Please provide the nomogram you will be using to produce the patterns of ablation.

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 1D and < 35% were within 0.5D; less than 60% achieved BUCVA > 20/40; complication and adverse events occurred in > 2% of the cases.

4. Please indicate what Operating System your computer is using.

5. Please provide a beam path and narrative description (with diagrams) of the subsystem and components of the operating microscope subsystem, including geometry and eye illumination levels (provide microscope lamp specifications and whether or not illumination is changed for different indications).

6. On page 62 you indicate that the beam divergence is 4°. This seems quite large, since beam divergence for these types of refractive lasers is usually on the order of fractions of a degree. Please specify in milliradians what the beam divergence is following the last focussing lens and explain any large divergence (> 50 milliradians).

7. 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.

8. Please clarify why you have omitted or modified the following inclusion criteria (Section 3.2.4.1):

   a. BSCVA should be 20/40 or better in both eyes.

   b. Contact lens wearers should:

      i. remove soft or gas permeable contact lenses two weeks prior to baseline measurements

      ii. remove hard contact lenses three weeks prior to baseline measurements, and have two central keratometry readings and two manifest refractions taken at least one week apart that do not differ by more than 0.50 diopter in either meridian; mires should be regular.

   c. Spherical or cylindrical portion of manifest refraction should progress 0.50 diopter or less during the year prior to the baseline exam.

   d. Subjects should be willing and capable of returning for follow-up examinations for the duration of the study.

   e. Videokeratography should be normal.

9. Please clarify why you have omitted or modified the following exclusion criteria (Section 3.2.4.2):

   a. Taking systemic medications likely to affect wound healing, such as corticosteroids or antimetabolites

   b. Immunocompromise (e.g., AIDS, autoimmune disease)

   c. Unstable central keratometry readings with irregular mires

   d. History of glaucoma or an intraocular pressure > 21 mm of Hg.

10. 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. Standard references may be used for generally accepted tests and instruments, but distances, luminances, and other settings should be provided.

11. On page 134 of your submission you have presented a sample of your Intraoperative Report Form. Operative reports should be completed for all treated subjects, and for those subjects on whom a procedure was attempted but not completed. In addition, the report should include the information on attempted spherical correction, attempted cylindrical correction, number of laser pulses, time for entire procedure, whether procedure was interrupted, drug treatment before, during and after the procedure, and which eye was treated first (and second). Report forms should be in a forced-choice format. Please revise your intraoperative report form or present justification for not conforming with the above recommendations.

12. Please provide a copy of your patient questionnaire.

13. You have indicated that cylinder will be evaluated based on desired versus achieved correction. However, since your study design involves a high degree of astigmatism (up to -7 D), please provide a plan to stratify your results also by astigmatic presentations. Also, for the astigmatic corrections, please report the proportion of eyes that achieve minimal residual astigmatism.

14. In your Informed Consent Document, page 197, please correct or justify the following:

    a. please provide a statement in one of the initial paragraphs that the study involves research;

    b. please provide a statement of the expected duration of the subject's participation;

    c. please delete the last sentence in the second paragraph on page 198, which begins, "However, this laser was developed by Dr. Nevyas...."; and,

    d. please correct the typographical errors on page 199 which mention Drs. Wong & Thorne.

15. All co-managing practitioners are considered investigators and must sign the investigator agreement prior to their participation. Please certify that all investigators (and co-managers) who will participate in the investigation have signed [illegible] Agreement.

FDA 8003

16. 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.

On page 93 of your submission you give the name and address of your Institutional Review Board (IRB). You are advised that your IRB should be composed and conducted in accordance with 12 CFR Part 56 and that members of the IRB should conform to 21 CFR 56.107 (e): "No IRB may have a member participate in the IRB's initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB."

If you submit information correcting the deficiencies, we will reevaluate your application. The information should be identified as an IDE amendment referencing the IDE number above, and must be submitted in triplicate to:

IDE Document Mail Center (HFZ-401)
Center for Devices and Radiological Health
Food and Drug Administration
9200 Corporate Boulevard
Rockville, MD 20850

Alternatively, you may request a regulatory hearing regarding the disapproval of your IDE application. The enclosure "Procedures to Request a Regulatory Hearing" describes how to submit such a request. The procedures governing a regulatory hearing are described in the regulations at 21 CFR Part 16.

If you prefer not to request a regulatory hearing, you may nevertheless request that this decision be reviewed by the IDE Review Committee within the Office of Device Evaluation (ODE). The enclosure entitled, "IDE Review Committee and Procedures to Request Review" discusses the purpose and operation of the Committee as well as how to submit such a request to the Committee.

If you have any questions, please contact Everette T. Beers, Ph.D. at (301) 594-2018.

Sincerely yours,

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosures
(1) Procedures to Request a Regulatory Hearing
(2) IDE Review Committee and Procedures to Request Review

AUG 0 6 1997

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 29 1997

Herbert J. Nevyas, M.D.
Nevyas Eye Associates
Delaware Valley Laser Surgery Institute
333 City Line Avenue
Bala Cynwyd, PA 19004

Re: G970088/A1 and A3
Device name: Sullivan Excimer Laser System (Nevyas Model)
Dated: July 3 and 21, 1997
Received: July 8 and 22, 1997

Dear Dr. Nevyas:

On July 8 and 22, 1997, the United States Food and Drug Administration (FDA) received the amendments to your investigational device exemption (IDE) application that you submitted for your excimer laser system for use in refractive eye surgery. FDA has started to review this application. We have determined, however, that additional information is required in order to complete this review.

Excimer laser systems are Class III devices within the meaning of section 513(f) of the Federal Food, Drug, and Cosmetic Act (the Act). Accordingly, a physician may not use an excimer laser system to treat patients unless there is in effect an approved premarket approval application (PMA) or an approved IDE for that device.

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.

FDA 0 0013

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. To enable FDA to complete its review of your IDE application, we also requested that you provide the agency with the following additional information: a written statement that, as of the close of business on July 28, 1997, you are not using your excimer laser system to treat patients. Please complete the enclosed statement and transmit it to:

Morris Waxler, Ph.D.
Food and Drug Administration
Center for Devices and Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ401)
9200 Corporate Blvd.
Rockville, MD 20850

You may submit the statement by facsimile to (301) 480-4201, provided that you also send the original statement to the address above. This statement must be submitted within three (3) business days of the receipt of this letter.

You should be aware that FDA's regulations provide that an IDE application may be disapproved if "[t]here has been a failure to comply with any requirement of [21 C.F.R. Part 812] or the Act . . . ," 21 C.F.R. § 812.30(b)(1); thus, any previous use of an excimer laser system for which no PMA or IDE is in effect would be grounds for disapproval of an applicant's IDE. However, the agency, in an exercise of its enforcement discretion, does not intend to consider your previous use, if any, of such a device to be grounds for disapproval of your IDE. 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. In addition, please note that failure to "respond to a request for additional information within the time prescribed by FDA" also would be grounds for disapproval of your IDE. 21 C.F.R. § 812.30(b)(3).

Furthermore, if you are, in fact, using an unapproved laser, failure to cease treating patients with the laser immediately also may result in regulatory action against you or the device by FDA without further notice. These actions include, but are not limited to, seizure, injunction, and civil money penalties.

FDA 0 0014

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. The IDE process is designed to investigate the safety and effectiveness of devices either for research or for market authorization, and is not itself a means of market authorization for the commercial treatment of patients. Once studies under your IDE were complete, you would not be able to use your laser unless you were to seek a PMA and FDA were to approve it.

If you have any questions about this request, you may contact Everette T. Beers, Ph.D. at (301) 594-2018.

Sincerely,

Nancy C Brogdon for

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic Devices
Office of Device Evaluation
Center of Devices and
Radiological Health

Enclosure

FDA 0 0015

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Herbert J. Nevyas, M.D.
Nevyas Eye Associates
Delaware Valley Laser Surgery Institute
333 City Line Avenue
Bala Cynwyd, PA 19004

AUG 7 1997

Re: G970088/A1, A3 and A4
Sullivan Excimer Laser System (Nevyas Model)
Indications for Use: LASIK for Myopia (-0.5 to -6.75 Diopters with up to -7 D Astigmatism)
Dated: July 3, 21, and 29, 1997
Received: July 8 and 22, and August 1, 1997
HCFA Reimbursement Category: A2 (for procedures to request re-evaluation of this categorization decision, please see the appropriate enclosure)
Annual Report Due: August 7, 1998

Dear Dr. Nevyas:

The Food and Drug Administration (FDA) has reviewed the amendments to your investigational device exemptions (IDE) application. Your application is conditionally approved because you have not adequately addressed deficiency #2 cited in our May 8, 1997 disapproval letter. You may begin your investigation, using a revised informed consent document which corrects deficiency #1 (below), after you have obtained institutional review board (IRB) approval, and submitted certification of IRB approval to FDA. 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 application for your device. You are reminded that when the agency has approved (conditionally or otherwise) an IDE for a device, all treatments with that device after the date of FDA approval of the IDE are treatments under the IDE; consequently, the device may be used to treat only the number of subjects approved in the IDE and only for the indications approved in the IDE. Your investigation is limited to one institution and 100 subjects for Low Myopia (-0.5 to -6.75 D) plus Astigmatism (up to -7 D).

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:

FDA 0 0016

1. Since your ablations are clearly non-spherical, as well as multifocal, you should provide a much stronger caution to your prospective subjects regarding the ability to see well in low light level situations. Please amend

with low illumination and low contrast as you see during the day; these situations may include, but are not limited to, nighttime, fog, dimly lit rooms. It is possible that you may not be able to drive at night. You should take precautions in situations where you may be at risk, because of your possible decreased visual acuity in the above situations. It is also possible that your eyes will become more tired than usual toward the end of the day."

Based on your patient questionnaires, you may be able to reassess this caution and provide to your patients some idea of the percentage of patients experiencing moderate to significant difficulty in seeing well in low light level situations. At PMA time, patient questionnaires can be reviewed by you and the agency for appropriate PMA labeling regarding the caution for low light level situations. In addition if you wish, you may conduct a substudy for contrast sensitivity and use this data as additional information for your PMA patient labeling or to reassess your IDE caution.

2. Because of concern about the non-spherical and multifocal properties of your ablations, please add the following to your patient questionnaire:

   a. a question regarding the patient's pre- and post-op ability to see well in low light level situations, such as in the dark, in dimly lit rooms or auditoriums, while driving at night, etc.; and,

   b. a question regarding how tired the patient's eyes become in the evening.

3. In addition to the times already specified in your protocol, your patient questionnaire should be administered at the one week, one month and six month visits.

4. Additional information is required regarding your PMMA ablations:

   a. Your PMMA ablations appear to be wider at the bottom than the algorithm predicts; for instance, most of the ablations are 2. FDA wide at the bottom, rather than 2.0 mm. Please explain what cau difference in width.

   b. Your PMMA ablations also appear to have a "hump" in the bottom of each ablation of about 10% to 20% of the maximum depth. Please explain what causes these "humps".

profiles near the area where the dark blue and light blue areas meet. Please explain what causes this "scalloped" appearance.

5. Since your ablation equations do not appear to follow Munnerlyn's equations for generating a spherical correction on the cornea, it is unclear how you have verified that your ablation pattern and depth for any particular correction will actually produce the desired effect, i.e., the required dioptric change. For instance, using your high myopia ablation algorithm to produce a -12 D correction, please demonstrate how you have verified that removing 98.75 microns of tissue in the manner specified (single zone, multipass) produces a -12 D correction. What difference would it make if one removes 90 microns or 110 microns? How have you verified the other ablation parameters for ablations in both the low myopia and high myopia algorithms?

6. Regarding the total tissue removed, there appears to be a disconnect between your theoretical ablation algorithms (Amendment 1, page 40) and the ablation parameters in Amendment 3. For instance, on page 40 of your Amendment 1, a -6.0 D ablation should remove 61.8 microns of tissue, while a -7.0 D ablation should remove 70.6 microns. On the other hand, on page 7 of Amendment 3 you show that a -6.75 D ablation has a maximum ablation depth of 77 microns (greater even than the -7.0 predicted in Amendment 1). Please explain these differences.

7. In response to Deficiency # 2.d. about etch rate, you indicated that the etch rate was 0.194 microns per pulse in PMMA and 0.25 microns per pulse in tissue.

   a. Our description of this deficiency probably was unclear. Please provide the etch rate *curve*, showing the laser energy per pulse versus the tissue (or PMMA) removed. Relate PMMA removed to tissue removed (this would be a ratio, for instance).

   b. The etch rate of 0.194 microns per pulse in PMMA and 0.25 microns per pulse in tissue produces a ratio of 1.29. However, when the tissue ablation on page 7 of Amendment 3 is divided by the PMMA ablation taken from the PMMA ablation profiles, this ratio appears to vary with the number of pulses delivered, ranging from 1.25 at an ablation of -1 D to 1.48 at an ablation of -6.75 D. Please explain this discre variation.

8. You have not adequately addressed Deficiency #5 in our letter of May 8, 1997 regarding the beam path for the operating microscope and subsystems. Please provide a ray trace which also shows how the microscope is positioned in referen e to the subject's eye, the aiming laser, the treatment laser, the fixation lights, etc.

9. Although you indicate that the COMPex 201 laser engine has a divergence of 3 milliradians/meter, please provide the divergence for your laser system after the last focusing lens.

10. In your description of the operative procedure, please specify the thickness of the corneal flap that is cut and reflected prior to ablation.

11. Please correct your protocol, page 19, to reflect that soft contact lenses will be lef out for at least 3 days prior to examination and surgery.

12. Please provide additional *technical* information regarding the methods of obtainir g and maintaining both temporal and spatial beam homogeneity.

This information should be identified as an IDE supplement referencing the IDE number above, and must be submitted in triplicate to:

IDE Document Mail Center (HFZ-401)
Center for Devices and Radiological Health
Food and Drug Administration
9200 Corporate Boulevard
Rockville, MD 20850

If you do not provide this information within 45 days from the date of this letter, we may take steps to propose withdrawal of approval of your IDE application.

We acknowledge your request to conduct a study at one site with approximately 990 eyes f r each of two investigators. We believe that adequate safety information has been provided t allow the initiation of your study at one site with 100 subjects; however, issues remain whi h must be resolved prior to the expansion of your study for marketing approval. Prior to your request for expansion beyond 100 subjects, you should submit the results of this initial pha e after 50% of the subjects have achieved at least 3 months of follow-up. FDA 0 0019

We would like to point out that FDA approval of your IDE application does not imply th t this investigation will develop sufficient safety and effectiveness data to assure FDA approval of a premarket approval (PMA) application for this device. You may obtain the guideline or

the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (30) 443-6597.

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. Also enclosed is the guidance document "Investigators' Responsibilities for a Significant Risk Device Investigation" which you should provide to participating investigators.

If you have any questions, please contact Everette T. Beers, Ph.D. at (301) 594-2018.

Sincerely yours,

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosures
(1) Procedures to Request Re-Evaluation of HCFA Reimbursement Categorization Determination
(2) Sponsor's Responsibilities for a Significant Risk Device Investigation
(3) Investigators' Responsibilities for a Significant Risk Device Investigation

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administratic
9200 Corporate Boulevard
Rockville MD 20850

OCT - 3 1997

Herbert J. Nevyas, M.D.
Nevyas Eye Associates
Delaware Valley Laser Surgery Institute
333 City Line Avenue
Bala Cynwyd, PA 19004

Re: G970088/S2, S3, and S4
Sullivan Excimer Laser System (Nevyas Model)
Indications for Use: LASIK to correct myopia of -0.5 to -15 Diopters (D) with up to -7 D of astigmatism for protocol NEV-97-001 Myopia; and, LASIK enhancement to correct myopia of eyes previously treated with this laser
Dated: August 28, September 10 and September 19, 1997
Received: September 9, 12, and 22, 1997
Annual Report Due: August 7, 1998

Dear Dr. Nevyas:

The Food and Drug Administration (FDA) has reviewed supplements 2, 3 and 4 to your investigational device exemptions (IDE) application. Supplement 2 requests a protocol deviation to treat two anisometropic patients (one eye at -10 D and one eye at -7.50 D); you were granted permission by telephone on September 9 to treat these two anisometropic patients. 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 in treatment range from -6.75 D to -22 D; approval to study simultaneous bilateral treatment; and, approval to retreat approximately 125 patients previously treated with this laser prior to IDE approval.

FDA cannot approve your request to study LASIK in higher myopes up to -22 D because you have not provided adequate data to support safe use above -15 D. FDA will conditionally approve, however, a study at this time of LASIK in 25 subjects with myopia -7 D to -15 D with up to -7.00 D of astigmatism; please see the conditions of approval below. If you agree to conduct your investigation within the modified limit, you may implement that change at the institution enrolled in your investigation where you have obtained institutional review board (IRB) approval. If you do not agree to this modified limit, you should consider this letter as a disapproval of your request for an expansion of the investigation, and you have an opportunity to request a regulatory hearing as described in the enclosure "Procedures to Request a Regulatory Hearing."

FDA 0 0021

FDA cannot approve your request to study enhancements on up to 125 of your prior clinical

and the time point of stability of, the procedure. FDA will conditionally approve, however, a study at this time of LASIK enhancement in 25 subjects previously treated with your laser; please see the conditions of approval below. Requests for additional subjects for enhancements for prior clinical patients will be evaluated as additional data is submitted to support stability of the procedure. If you agree to conduct your investigation within the modified limit, you may implement that change at the institution enrolled in your investigation where you have obtained institutional review board (IRB) approval. If you do not agree to this modified limit, you should consider this letter as a disapproval of your request for an expansion of the investigation, and you have an opportunity to request a regulatory hearing as described in the enclosure "Procedures to Request a Regulatory Hearing."

We regret to inform you that your request to study simultaneous bilateral LASIK treatment is disapproved and you may not implement the expansion of your investigation. Our disapproval is based on the following deficiency:

> If you wish to study simultaneous bilateral LASIK surgery, you should propose a substudy comparing simultaneous with sequential treatment to establish the safety of the simultaneous procedure. Your substudy should contain satisfactory preliminary data on the safety, effectiveness and stability of the procedure on the primary eyes. In your substudy you should specify the time between surgeries for each eye and any criteria used to determine when to treat the fellow eye; time between surgeries and treatment criteria should be specified for both simultaneous and sequential procedures.

If you submit information correcting the deficiency, FDA will reevaluate the proposed expansion of the investigation. Alternatively, you may request a regulatory hearing regarding the disapproval of your IDE supplement. The enclosure "Procedures to Request a Regulatory Hearing" describes how to submit such a request. The procedures governing a regulatory hearing are described in the regulations at 21 CFR Part 16.

Also, FDA acknowledges the telephone conversation between you and Dr. Beers of the FDA on August 25, 1997 in which you were granted permission to perform simultaneous bilateral surgery on two subjects because of pressing personal needs of the subjects.

Your response to FDA conditional approval letter of August 7, 1997, remains conditionally approved because you adequately addressed only deficiencies 1, 2, 3, 4, 6, 7a, 8, 9, 10, and 11. You may continue your investigation at the institution where you have obtained IRB approval and submitted certification of IRB approval to FDA. Your investigation is limited to 1 institution and 150 total subjects: 100 subjects for low myopia (from -0.5 to -6.75 D), 25 subjects for high myopia (from -7.00 to -15 D), and 25 subjects for enhancements of prior

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.

1. Your device does not have a fail-safe mechanism for automatically shutting down your laser in the event of inappropriate energy output from the laser. Please submit an engineering plan and time-table for retrofitting your device with an adequate fail-safe mechanism. This mechanism should include a safe means to complete the treatment.

2. You agree to submit monthly reports of the subjects treated with your investigational laser identifying them by a unique subject identifier, date treated, and indication for treatment.

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.

This information should be identified as an IDE supplement referencing the IDE number above, and must be submitted in triplicate to:

IDE Document Mail Center (HFZ-401)
Center for Devices and Radiological Health
Food and Drug Administration
9200 Corporate Boulevard
Rockville, MD 20850

If you do not provide this information within 45 days from the date of this letter, we may take steps to propose withdrawal of approval of your IDE application.

We acknowledge your request to conduct a study at one site with approximately 990 eyes for each of two investigators. We believe that adequate safety information has been provided to allow the initiation of your study at one site with 150 subjects; however, issues remain which must be resolved prior to the expansion of your study for marketing approval. Prior to your request for expansion beyond 150 subjects, you should submit the results of this initial phase after 50% of the subjects have achieved at least 3 months of follow-up.

Prior to your request for expansion beyond 150 subjects, you should submit adequate responses to the following deficiencies. Incremental expansions beyond 150 subjects may be

Calibration:

5. Your description of the beam calibration is inadequate. Specifically, you should provide:

   a. description of the method, technical specifications of any substrates used, validation procedures for the tests, and passing criteria for energy (fluence), homogeneity, beam alignment, and any other calibration procedures;

   b. information on how instrument measurement precision was determined, and a calibration schedule;

   c. a diagram of the measurement set up (i.e., for opening the "beam shaping aperture") and test firing;

   d. the technical specifications of the Chiron substrate used for measurements so that the number of pulses and the irradiance level(s) that provide for breakthrough and complete removal for the substrate material can be verified;

   e. a statistical analysis used for the determination of energy stability;

   f. a technical description of the transparent substrate used for beam homogeneity determination and a description of how the scientific accuracy and validity of the test was determined;

   g. descriptions of any differences between the output beam measurement and homogeneity tests using a substrate of known thickness and ablation characteristics; and,

   h. a description of how the device software determines the energy output needed during the calibration process.

Laser Characteristics:

6. The energy output of your aiming lasers, each at 1 mW, is high relative to the other aiming lasers that we have encountered. Please determine the exposure hazard per CFR 1040.10 and specify the maximum exposure time.

7. Does your laser system have the capabilities to treat other refractive conditions that are not described in this application and which are not disabled for this clinical trial? If the answer is "yes", then please indicate the steps taken to ensure that the device will not be used outside the approved protocol(s).

8. The electrical safety information provided applies only to the Lambda Physik excimer laser, not the complete device as required by FDA. Also, the standards cited are German standards which to date have not been accepted by FDA. You are reminded that you should provide electrical certification for the *entire system*, including the laser, motors, other electrical devices which connect to the laser, electrically operated chairs, etc. Please provide certification that the device conforms to a recognized national or international electrical safety standard for medical devices (e.g., Underwriters Laboratories, UL544 76, UL-2601 for Medical Equipment Systems; Canadian Standards Association, C22.2 No.125-M1984; British Standards Institute, BS 5724; International Electrotechnical Commission, IEC 601-1; Japanese Industrial Standard, JIS T1001; or, equivalent).

9. Although you provided the ray trace for the microscope section, the ray trace diagram in tab 3.4.1.3.B-2 (original IDE) does not show how the optics along the delivery path condition the beam, and the beam imaging module is not adequately depicted or described in the submission. Please provide more detailed information on both of these items and address the comments below:

   a. The optic diagram (3.4.2.2.A.4 on page 78) needs a ray trace to show how all the components function to condition the beam from the raw beam output to projection onto the corneal surface.

   b. The beam imaging module has not been adequately described. Please describe the components of the beam imaging module, their specifications, a diagram with ray trace diagram to illustrate the optical design, and the manner in which the intended functions are attained.

10. Please provide the following information about your laser system:

   a. please specify the cavity type for your laser: stable or non-stable; and,

   b. please specify the stability of the pulse through the gas lifetime and indicate how this was determined.

Ablation Algorithms and Profilometry:

11. You stated in supplement 4 that the etch rate curve is being generated; therefore, this remains a deficiency. Please provide the etch rate *curve*, showing the laser energy per pulse versus the PMMA removed, for energy levels above and below your treatment energy level. Provide the expected etch rate in tissue

Relate the amount of PMMA removed per pulse to the amount of tissue removed per pulse (this would be a ratio, for instance).

12. The formulation of the equation for the device ablation algorithm in Section 3.4.1.3.A "Ablation Patterns" is inadequate. Your description of the theoretical ablation algorithm appears to be internally inconsistent and lacks mathematical clarity. Please address the following:

a. Why were 2 definitions provided for the same mathematical quantity c1(), and c2() as "curvatures" of the uncorrected and corrected cornea respectively, and simultaneously as "distances from an arc to a chord"? This information appears incorrect for the following reasons:

Curvature is a mathematically defined quantity. It is defined as the angular velocity of the tangent to the curve as the tangent traverses and therefore describes the given curve. In the rectangular coordinate (as provided in your submission) an angle phi is defined as the angle between the tangent and the curve, and this angle phi is the arc-tangent of the first derivative of the spatial coordinates of the curve with "x" as the independent variable. In fact, the diagram you submitted illustrates "2 intersecting curves, labeled by the sponsor as c1(), and c2(), which represent a 2 dimensional cross section of the uncorrected and corrected cornea." It is illogical for them to be described as anything else. There cannot be 2 intersecting curves and "distances to an arc to a chord" at the same time as you described.

The final equation [now labeled as (4)] does not appear to be one which can be related to ablation of the cornea because it is an equation which contains only spatial coordinates and no dependence on D (the dioptric power), or n (the index of refraction of the cornea). The statement that d(y) represents the depth at any spherical coordinate Y appears logically inconsistent because the equation is formulated in rectangular coordinates, and the equation has no Y dependence. In order to derive the ablation equation, one has to use the geometry of the 2 intersecting curves to set up an equation for the depth between the 2 curves as a function of Y where Y is defined as the lateral distance from optical axis of the cornea. At this point one has to get the dependence of D, and n into the geometrical equation by making appropriate substitutions from the equation for the power of a lens which is an independent equation. The result of these operations is a very complicated expression which is simplified by applying the binomial expansion to it. At this point a further simplification is made by finding the depth of cut on the corneal optical axis. This means let Y=0. The resulting simple equation is for t(on axis depth)= optical zone diameter squared times dioptric change divided by eight times the difference between the indices of refraction of the cornea and air. This is the so-called Munnerlyn equation.

b. You should supply scientific references applicable to the derived equation, and include all mathematical steps leading to the equation. You have not furnished the requested scientific references, nor the intermediate mathematical steps. Please provide this information.

c. You should provide an explanation of the reasons that D (power in diopters), and n (index of refraction of the cornea) do not appear in the ablation equation, and why the coordinate Y is undefined; no information has been provided explaining why the ablation equation has no D, or n dependence. As discussed previously, the explanation that Y is any spherical coordinate on the y axis is logically inconsistent.

d. You should identify the ablation axes for c1() and c2().

e. Please indicate how the derived equation is integrated into the device software to provide calculations that are required for the targeted corrections.

13. The theoretical fits to the profilometric data are based on 8th order polynomials. It is not clear what theory this procedure is based on and is apparently in qualitative disagreement with the data in the central 2 mm and outside the ablation zone. The appropriate theoretical fits should be to circular contours, since the ablations are supposed to approximate Munnerlyn's equations. Typically, one determines the theoretical mathematical ablation curve (i.e., the theoretical curve), employs hardware and software to approximate the mathematical curve (i.e., the programmed ablation curve), then measures the resultant ablation curve (i.e., the actual ablation curve in PMMA, for instance). It is not clear what is the theoretical curve to which you are trying to match your ablation curves (programmed and actual).

a. Please provide additional explanation regarding the theoretical ablation curves (mathematical equations) which you are trying to approximate with your hardware and software.

b. Please discuss how the programmed pattern described on pages 57-61 (Original IDE) and summarized in attachment 2.A-3 (Amendment 1, dated July 3, 1997) approximates the theoretical pattern described on pages 56-57 (Original IDE); plots of the programmed patterns versus the theoretical patterns would be helpful in this discussion.

Multifocality:

14. Your ablation patterns for correcting myopia and astigmatism do not appear to be spherical and cylindrical, respectively, and, therefore, cannot provide a single dioptric

correction of refractive error. The intended (theoretical) myopic ablation is flat (i.e., constant depth) over the central 2 mm, and decreases in depth in five linear segments of decreasing slope, with the five annular segments extending from diameters of 2 to 3 mm, 3 to 3.9 mm, 3.9 to 4.8 mm, 4.8 to 5.7 mm and 5.7 to 6.6 mm. The actual ablation is not flat in the central 2 mm, but shows a pronounced "central island" so that the ablation depth is up to 20% less at the center than at 2 mm diameter. The central 2 mm thus receives a hyperopic instead of a myopic correction. Outside the central 2 mm, the ablation produces a cornea with constantly changing curvature, i.e., constantly changing dioptric power. The amount of correction varies from overcorrection near 2 mm to undercorrection near 6.6 mm. Although the smoothing effect of the overlying corneal flap may modify this shape to some extent, it seems likely that the smoothing effects will be limited to distances no more than a few tenths of a mm from discontinuities in the ablation pattern. The predicted result of this type of ablation is a multifocal cornea, in which different portions of the cornea simultaneously focus portions of the "retinal" image at different positions in front of, on, or behind the retina. This multifocal property raises a number of safety and effectiveness issues that you will need to address:

a. An eye with a multifocal cornea generally will not have a well-defined best distance refraction. Uncorrected visual acuity as a function of distance may be nearly constant over an extended range, or it may be complex, with multiple peaks and troughs. Characterizing the refractive state may be difficult, requiring visual acuity assessments over a range of refractive corrections. Please provide a detailed description of the procedures you will use for measuring manifest refractions for postoperative subjects to take into account these concerns.

FDA 0 0028

b. To document the clinical effects of this multifocal ablation, please propose substudies for mesopic contrast sensitivity (or low contrast acuity) with and without glare. The background luminance of the contrast sensitivity test should be reduced to less than 3 cd/m² (about 0.2 cd/m² preferred) and the ambient illumination should be even lower. The test targets may be either grating contrast sensitivity charts or low contrast letter acuity charts. In order to limit pupil constriction and maintain uniform glare conditions across the test chart, the glare source should be an array of two or more small spots symmetrically positioned around the chart. The glare source should be bright enough to significantly reduce the contrast sensitivity of young adult subjects with normal corneas and normal vision. If the above conditions cannot be implemented, the Brightness Acuity Test (BAT) may be used as an alternative glare source if the subject's pupil is dilated and the above brightness criterion is met. Control data may be obtained either from the preop LASIK subjects or (preferably) from a sample of normal subjects with the same age, gender and refractive error distributions as the postoperative test subjects.

differences with 80% power (e.g., if the standard deviation is 0.3 log unit, about 80 subjects would be needed to meet this target). Postoperative testing should be conducted after visual function has stabilized.

c. If contrast sensitivity testing shows decreased sensitivity under mesopic conditions, it may be possible that better results could be obtained using a different spectacle correction. Knowing the dioptric powers of your ablation could help in choosing appropriate spectacle correction, or provide a basis for adjusting your algorithm. As an aid to documenting the degree of multifocal performance predicted for corneas treated with your ablation algorithms, please provide graphs of either dioptric power or radius of curvature as a function of distance from the center of the ablation for representative myopic, elliptical and astigmatic ablation profiles.

d. Please obtain preoperative and postoperative (after achieving refractive stability) corneal topographic measurements, and provide difference maps and difference profiles showing the change in the contour of the corneal surface resulting from your LASIK procedure for a subset of your subjects treated under this IDE.

e. Please provide data to support your statement (page 8 of supplement 4) that lensometer measurement of the PMMA ablation profile verified the desired dioptric correction. Please provide data to show whether or not lensometer measurement shows more than one possible dioptric reading for the same ablation.

Homogeneity:

15. Your beam appears to be inhomogeneous with varying hot spots and cool spots across the treatment area of the beam. Although you stated in supplement 4 that you are exploring options for adding a beam homogenizer onto your laser, the question regarding homogeneity remains a deficiency. In addition, since calibration is a part of maintaining beam homogeneity, you should address the questions above regarding beam calibration. Please provide additional technical details regarding your methods of obtaining (i.e., conditioning optics) and maintaining (e.g., calibration and maintenance) temporal and spatial beam homogeneity, including the range (tolerances) of acceptable values for homogeneity and data to support your findings.

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:

Software:

16. Your description of your software is inadequate. Please address the following:

a. Hazards Analysis: Please submit a more detailed Hazard Analysis which provides a description of the hazards presented by this device to the subject, the causes of these hazards, and the methods used to eliminate or mitigate them. This analysis should specifically identify the system hazards, and the components whose failure could cause those hazards and which are controlled by or interact with software. The analysis should identify this controlling or interacting software, and describe in greater detail how errors in this software are controlled or mitigated throughout the software development process.

b. Functional Requirements and System Specifications: Please provide a much more detailed description of the system and software requirements and specifications, including safety critical functions implemented because of the ongoing hazards analysis, and any applicable algorithms.

c. Software Design and Development: Please submit your written procedures, or at a minimum a very detailed description of your procedures, for designing and developing the software to be used in the device, from concept to delivery to the customer.

d. Verification, Validation, and Testing: Please submit a more detailed description of the software verification, validation, and testing process, including but not limited to the techniques and methods used at the module, integration and system level, the testing strategies and methodologies, and the test acceptance and completion criteria. Include examples and documentation of testing results.

e. Revision Control: Please submit the written procedures, or at a minimum, a very detailed description of the procedures, for your revision control process.

Advisory:

Although we requested the patient questionnaire be administered at times in addition to the ones you had originally proposed, we now believe that the subjects may become acclimated to the questionnaire, if it is presented too frequently. Therefore, you may revert to the times originally proposed in your IDE.

If you have any questions, please contact Everette T. Beers, Ph.D. at (301) 594-2018.

Sincerely yours,

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic Devices
Office of Device Evaluation
Center for Devices and Radiological Health

~~Enclosure: "Procedures to Request a Regulatory Hearing"~~

DEC 19 1997

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 16 1997

Herbert J. Nevyas, M.D.
Nevyas Eye Associates
Delaware Valley Laser Surgery Institute
333 City Line Avenue
Bala Cynwyd, PA 19004

Re: G970088/S5
Sullivan Excimer Laser System (Nevyas Model)
Indications for Use: LASIK to correct myopia of -0.5 to -15 Diopters (D) with up to -7 D of astigmatism for protocol NEV-97-001 Myopia; and, LASIK enhancement to correct myopia of eyes previously treated with this laser
Dated: November 12, 1997
Received: November 17, 1997
Annual Report Due: August 7, 1998

Dear Dr. Nevyas:

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. You may continue your investigation at the institution where you have obtained institutional review board (IRB) approval. Your investigation is limited to one institution and 150 subjects: 100 subjects for low myopia (-0.5 to -6.75 D myopia plus up to -7 D astigmatism); 25 subjects for high myopia (-7 to -15 D with up to -7 D astigmatism); and, 25 subjects for enhancements of previously treated subjects (-0.5 to -15 D myopia with up to -7 D astigmatism).

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:

1. You have stated that you currently are working on plans for a fail-safe mechanism for your device. Please submit an engineering plan and time-table for retrofitting your device with an adequate fail-safe mechanism. This mechanism should include a safe means to complete the treatment.

FDA 0 0032

2. Regarding retreatments (enhancements), your data do not appear to support enhancement after 8 weeks postoperatively. It is possible that there is merely a matter of differences in interpreting your data. Please provide your stability data according to the tables enclosed (see enclosure, "Stability of Manifest Refraction"). Also, please submit a retreatment study plan. You may begin retreatment procedures only after FDA has reviewed that data and approved your retreatment study plan.

This information should be identified as an IDE supplement referencing the IDE number above, and must be submitted in triplicate to:

IDE Document Mail Center (HFZ-401)
Center for Devices and Radiological Health
Food and Drug Administration
9200 Corporate Boulevard
Rockville, MD 20850

If you do not provide this information within 45 days from the date of this letter, we may take steps to propose withdrawal of approval of your IDE application.

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.

If you have any questions, please contact Everette T. Beers, Ph.D. at (301) 594-2018.

Sincerely yours,

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure:
Tables for Stability of Manifest Refraction

FDA 0 0033

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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9200 Corporate Boulevard
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JAN 1 4 1998

Herbert J. Nevyas, M.D.
Nevyas Eye Associates
Delaware Valley Laser Surgery Institute
333 City Line Avenue
Bala Cynwyd, PA 19004

Re: G970088/S6
Sullivan Excimer Laser System (Nevyas Model)
Indications for Use: LASIK to correct myopia of -0.5 to -15 Diopters (D) with up to -7 D of astigmatism for protocol NEV-97-001 Myopia; and, LASIK enhancement to correct myopia of eyes previously treated with this laser
Dated: December 11, 1997
Received: December 15, 1997
Annual Report Due: August 7, 1998

Dear Dr. Nevyas:

The Food and Drug Administration (FDA) has reviewed the supplement to your investigational device exemptions (IDE) application proposing a plan for simultaneous bilateral LASIK. Your supplement is conditionally approved, and you may implement that change at the institution enrolled in your investigation. Your application remains conditionally approved because you have not addressed the deficiencies cited in our December 16, 1997 letter. You may continue your investigation at the institution where you have obtained institutional review board (IRB) approval. Your investigation is limited to 1 institution and 150 subjects: 100 subjects for low myopia (-0.5 to -6.75 D myopia plus up to -7 D astigmatism); 25 subjects for high myopia (- 7 to -15 D with up to -7 D astigmatism); and, 25 subjects for enhancements of previously treated subjects (-0.5 to -15 D myopia with up to -7 D astigmatism).

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:

In your "Substudy for Same-Day Versus Different Day LASIK Treatment for Fellow Eyes":

FDA 0 0034

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.

b. Those eyes rescheduled from same day to different day surgery should be accounted for.

c. If the exclusion criteria of the original protocol do not specifically mention the exclusion of patients with anterior segment lid diseases (e.g., blepharitis, etc.), then the substudy protocol should specifically exclude patients with these conditions for same day fellow eye surgery.

d. FDA believes that a one day interval is not sufficient to qualify as a "different day" procedure. It is recommended that the protocol for the substudy be altered to have a minimum 2-week waiting period prior to fellow eye treatment.

e. 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."

f. Please specify the minimum time between treatment of same day fellow eyes, in order to evaluate for complications. 1/2 hr.

g. These same day fellow eye subjects are considered part of your overall total, currently 100 eyes low myopia and 25 eyes high myopia.

This information should be identified as an IDE supplement referencing the IDE number above, and must be submitted in triplicate to:

IDE Document Mail Center (HFZ-401)
Center for Devices and Radiological Health
Food and Drug Administration
9200 Corporate Boulevard
Rockville, MD 20850

If you do not provide this information within 45 days from the date of this letter, we may take steps to propose withdrawal of approval of your IDE application.

If you have any questions, please contact Everette T. Beers, Ph.D. at (301) 594-2018.

Sincerely yours,

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic Devices
Office of Device Evaluation
Center for Devices and Radiological Health

APR 0 6 1998

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Herbert J. Nevyas, M.D.
Nevyas Eye Associates
Delware Valley Laser Surgery Institute
333 City Line Avenue
Bala Cynwyd, PA 19004

APR 1 1998

Re: G970088

Dear Dr. Nevyas:

You currently have an investigational device exemption G970088 for your laser. If you should ultimately wish to submit a premarket approval application (PMA) for this laser, please use the following guidance as to the type of information you need to submit to FDA regarding manufacture of your device.

If you do not intend to manufacture additional units of the excimer laser system that is the subject of your PMA, FDA will forego a Good Manufacturing Practices (GMP) inspection, but we will require you to submit manufacturing information in the Manufacturing Section of your PMA. In the past communications with your consultant, Barbara Fant, Pharm.D., we have stated that this information should include:

complete specifications for the laser unit, including operating parameters;

acceptance specifications for raw material and components;

a description of the complaint file procedures; and

procedures for change controls for any changes in the design of the one laser unit.

FDA 0 0037

The above-listed requirements are critical to the submission of your PMA Manufacturing Section, but cannot legally constitute a complete list of the information you will need to submit for this section. Section 515 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) requires that an application for premarket approval for a Class III device, such as yours, shall contain "a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and , when relevant, packing and installation of, such device." 21

justifies an omission in accordance with 21 C.F.R. 814.20(d), a PMA shall include a complete description of "[t]he methods used in, and the facilities and controls used for, the manufacture, processing, packing, storage, and, where appropriate, installation of the device, in sufficient detail so that a person generally familiar with current good manufacturing practice can make a knowledgeable judgment about the quality control used in the manufacture of the device."

You are responsible for providing all manufacturing information required under the FD&C Act and under FDA's regulations. In order to do so, you should consider in detail each section of FDA's Quality System Regulation, found at 21 C.F.R. Part 820 (reprinted in the Appendix to the Medical Devices Quality Systems Manual located at FDA's website, www.fda.gov/cdrh/dsma/cgmphome.html). If you decide not to manufacture additional units of your device and believe that specific types of manufacturing information are not applicable for your device as a result of this decision, you will be required to identify the omitted information and
justify the omission, in accordance with 21 C.F.R. 814.20(d).

If you have any questions about this letter please call Mary Lou Davis at (301) 594-4613.

Sincerely yours,

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic Devices
Office of Device Evaluation
Center for Devices and Radiological Health

FDA 0 0038

MAY 2 0 1998

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 1 4 1998

Herbert J. Nevyas, M.D.
Nevyas Eye Associates
Delaware Valley Laser Surgery Institute
333 City Line Avenue
Bala Cynwyd, PA 19004

Re: G970088/S8 & S9
Sullivan Excimer Laser System (Nevyas Model)
Indications for Use: LASIK (Laser-Assisted In Situ Keratomileusis) to correct myopia of -0.5 to -15 Diopters (D) with up to -7 D of astigmatism for protocol NEV-97-001 Myopia; and, LASIK enhancement to correct myopia of eyes treated with this laser prior to IDE approval.
Dated: April 12 and 14, 1998
Received: April 14 and May 8, 1998
Annual Report Due: August 7, 1998

Dear Dr. Nevyas:

The Food and Drug Administration (FDA) has reviewed the supplements to your investigational device exemptions (IDE) application. Supplement 8 proposed a plan for a contrast sensitivity substudy and provided a design for a fail-safe mechanism, and Supplement 9 requested additional high myopia subjects. Your plan for a contrast sensitivity substudy is conditionally approved, and you may implement that change at the institution enrolled in your investigation. Your design and time-table for a fail-safe mechanism is approved. Your request for additional high myopia subjects (- 7 to -15 D with up to -7 D astigmatism) is approved for an additional 25 subjects (50 eyes). In addition, your application is approved for an additional 50 subjects (100 eyes) for low myopia (-0.5 to -6.75 D myopia plus up to -7 D astigmatism).

Your application is approved because you have addressed the deficiencies cited in our December 16, 1997 letter. You may continue your investigation at the institution where you have obtained institutional review board (IRB) approval. Your investigation is limited to 1 institution and 225 subjects: 150 subjects (300 eyes) for low myopia (-0.5 to -6.75 D myopia plus up to -7 D astigmatism); 50 subjects (100 eyes) for high myopia (- 7 to -15 D with up to -7 D astigmatism); and, 25 subjects (50 eyes) for enhancements of subjects treated prior to IDE approval (-0.5 to -15 D myopia with up to -7 D astigmatism).

FDA 0 0039

Since FDA believes this change affects the rights, safety or welfare of the subjects, you must

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

Please submit your agreement that you will validate the proposed glare source prior to initiating this substudy. An appropriate validation would be a small control study with 5-10 normal emmetropic subjects. The glare source should just significantly raise contrast thresholds for these subjects. If it does not, the glare is too dim and will not be a sensitive measure of glare effects in LASIK subjects. In that case, the glare source will need to be brightened until it raises normal contrast thresholds.

This information should be identified as an IDE supplement referencing the IDE number above, and must be submitted in triplicate to:

IDE Document Mail Center (HFZ-401)
Center for Devices and Radiological Health
Food and Drug Administration
9200 Corporate Boulevard
Rockville, MD 20850

If you do not provide this information within 45 days from the date of this letter, we may take steps to propose withdrawal of approval of your IDE application.

We would like to point out that FDA approval of your IDE supplement does not imply that this investigation will develop sufficient safety and effectiveness data to assure FDA approval of a premarket approval (PMA) application for this device. You may obtain the guideline for the preparation of a PMA application, entitled "Premarket Approval (PMA) Manual," from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597.

You are reminded (see our letter of December 16, 1997) that you may not begin retreatment procedures on subjects treated under this IDE until FDA has reviewed your stability data and approved your retreatment study plan..

FDA 0 0040

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

Your contrast sensitivity substudy submitted in supplement 8 adequately addresses only deficiency 14.b., in our letter of October 3, 1997. Please submit adequate responses to deficiency 14, page 7, regarding probable multifocal properties of your ablation profiles and the need for procedures for post operative manifest refraction, graphs of dioptric power or radius of curvature as a function of distance from the center of the ablation, preoperative and post operative topographic difference maps, and lensometer measurements of the PMMA profile.

You also may want to consider incorporating into your laser system an additional algorithm to perform spherical ablations, so that you can compare in a clinical substudy your current ablation profile with a spherical ablation profile. We are available to meet with you to discuss our requirements for full approval, if you have any questions or wish further guidance.

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.

If you have any questions, please contact Everette T. Beers, Ph.D. at (301) 594-2018.

Sincerely yours,

Nancy C. Brogdon for

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure: Letter of October 3, 1997

FDA 0 0041

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 7 1998

Herbert J. Nevyas, M.D.
Nevyas Eye Associates
Delaware Valley Laser Surgery Institute
333 City Line Avenue
Bala Cynwyd, PA 19004

Re: G970088/S10
Sullivan Excimer Laser System (Nevyas Model)
Indications for Use: LASIK (Laser-Assisted In Situ Keratomileusis) to correct myopia of -0.5 to -15 Diopters (D) with up to -7 D of astigmatism for protocol NEV-97-001 Myopia; and, LASIK retreatment to correct myopia and myopic astigmatism.
Dated: June 3, 1998
Received: June 8, 1998
Next Annual Report Due: August 7, 1998

Dear Dr. Nevyas:

The Food and Drug Administration (FDA) has reviewed the supplement to your investigational device exemptions (IDE) application addressing glare testing validation and proposing an expansion of your investigation to include both myopic and hyperopic retreatments (enhancements). 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. If you agree to conduct your investigation within the modified limit (myopia and myopic astigmatism retreatments only), you may implement that change at the institution where you have obtained institutional review board (IRB) approval. Your investigation is limited to 1 institution and 225 subjects: 150 subjects (300 eyes) for low myopia (-0.5 to -6.75 D myopia plus up to -7 D astigmatism); 50 subjects (100 eyes) for high myopia (- 7 to -15 D with up to -7 D astigmatism); and, 25 subjects (50 eyes) for enhancements of subjects treated prior to IDE approval (-0.5 to -15 D myopia with up to -7 D astigmatism).

If you do not agree to this modified limit, you should consider this letter as a disapproval of your request for an expansion of the investigation, and you have an opportunity to request a regulatory hearing as described in the enclosure "Procedures to Request a Regulatory Hearing."

FDA 0 0042

Since FDA believes this change affects the rights, safety or welfare of the subjects, you must

This approval is being granted on the condition that, 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 with less than 1 diopter of change, confirmed by topography.

This information should be identified as an IDE supplement referencing the IDE number above, and must be submitted in triplicate to:

IDE Document Mail Center (HFZ-401)
Center for Devices and Radiological Health
Food and Drug Administration
9200 Corporate Boulevard
Rockville, MD 20850

If you do not provide this information within 45 days from the date of this letter, we may take steps to propose withdrawal of approval of your IDE application.

We would like to point out that FDA approval of your IDE supplement does not imply that this investigation will develop sufficient safety and effectiveness data to assure FDA approval of a premarket approval (PMA) application for this device. You may obtain the guideline for the preparation of a PMA application, entitled "Premarket Approval (PMA) Manual," from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597.

You should give serious consideration to the fact that your procedure does not appear to reach stability, as defined by stability of manifest refractions taken 3 months apart: 95% within 1 diopter, mean difference of ≤ 0.1, and a lower confidence limit of 90%. The appearance of instability of manifest refraction may be the result of unreliable or variable refractions having been taken by different persons using different instruments. In addition, you should continue to pursue follow-up on all subjects; it appears that you had 81 subjects eligible for the 3 month visit, yet only 67 were reported to FDA

Prior to your request to modify your protocol to provide hyperopic retreatments, you should

You indicated that you have performed hyperopic retreatments on your pre-IDE patients. Please provide any information you have on these patients regarding pre-retreatment visual acuity, amount of retreatment required, post-retreatment visual acuity and stability of manifest refraction, and any other information which would be appropriate in demonstrating that this procedure provides a stable retreatment of an overcorrected cornea.

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 will approve a request 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. No additional expansions of your IDE will be granted until supplements containing the following information are approved:

Your contrast sensitivity substudy submitted in supplement 8 adequately addresses only deficiency 14.b., in our letter of October 3, 1997. Please submit adequate responses to deficiency 14, page 7, regarding probable multifocal properties of your ablation profiles and the need for procedures for postoperative manifest refraction, graphs of dioptric power or radius of curvature as a function of distance from the center of the ablation, preoperative and postoperative topographic difference maps, and lensometer measurements of the PMMA profile.

You also may want to consider incorporating into your laser system an additional algorithm to perform spherical ablations, so that you can compare in a clinical substudy your current ablation profile with a spherical ablation profile. We are available to meet with you to discuss our requirements for full approval, if you have any questions or wish further guidance.

If you have any questions, please contact Everette T. Beers, Ph.D. at (301) 594-2018.

Sincerely yours,

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure:
"Procedures to Request a Regulatory Hearing."

FDA 0 0044

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 2 8 1998

SEP 2 4 1998

Herbert J. Nevyas, M.D.
Nevyas Eye Associates
Delaware Valley Laser Surgery Institute
333 City Line Avenue
Bala Cynwyd, PA 19004

Re: G970088/S12
Sullivan Excimer Laser System (Nevyas Model)
Indications for Use: LASIK (Laser-Assisted In Situ Keratomileusis) to correct myopia of -0.5 to -15 Diopters (D) with up to -7 D of astigmatism for protocol NEV-97-001 Myopia; and, LASIK retreatment to correct myopia and myopic astigmatism.
Dated: August 24, 1998
Received: August 27, 1998
Next Annual Report Due: August 7, 1998 (Extension granted to September 21, 1998)

Dear Dr. Nevyas:

The Food and Drug Administration (FDA) has reviewed the supplement to your investigational device exemptions (IDE) application addressing deficiencies in our July 7, 1998 letter regarding myopia and myopia plus astigmatism retreatments and addressing the deficiency in our letter of May 14, 1998 regarding validation of your glare source for contrast sensitivity testing. Your supplement proposing an expansion of your study for myopia and myopia plus astigmatism retreatments is approved. Your supplement regarding contrast sensitivity testing is conditionally approved. You may continue your investigation at the institution enrolled in your investigation. Your investigation is limited to 1 institution and 225 subjects: 150 subjects (300 eyes) for low myopia (-0.5 to -6.75 D myopia plus up to -7 D astigmatism); 50 subjects (100 eyes) for high myopia (-7 to -15 D with up to -7 D astigmatism); and, 25 subjects (50 eyes) for enhancements of subjects treated prior to IDE approval (-0.5 to -15 D myopia with up to -7 D astigmatism).

Since FDA believes this change affects the rights, safety or welfare of the subjects, you must also obtain institutional review board (IRB) approval before implementing this change in your investigation (21 CFR 812.35(a)).

This approval is being granted on the condition that, within 45 days from the date of this letter, you submit information correcting the following deficiency: FDA 0 0045

In the validation of your glare source for the contrast sensitivity study, you tested subjects at 2.5 cd without glare and at 2.5 cd with glare of 2 lux. The light level of

cycles per degree (CPD). However, the glare source of 2 lux appears to be too bright, since even the emmetropic subjects have significant reductions (50% to 80%) at all CPD. With this severe degree of impairment in normal subjects, there is very little additional decline, if any, that can be attributed to the study subjects. A small decrease of 10% to 30% with the glare source would show that the glare source was bright enough to affect normals, yet still be able to observe a decrease, if any, in the study subjects. Please re-validate this study using a less intense glare source; perhaps 1.5 lux would be appropriate.

This information should be identified as an IDE supplement referencing the IDE number above, and must be submitted in triplicate to:

IDE Document Mail Center (HFZ-401)
Center for Devices and Radiological Health
Food and Drug Administration
9200 Corporate Boulevard
Rockville, MD 20850

If you do not provide this information within 45 days from the date of this letter, we may take steps to propose withdrawal of approval of your IDE application.

We would like to point out that FDA approval of your IDE supplement does not imply that this investigation will develop sufficient safety and effectiveness data to assure FDA approval of a premarket approval (PMA) application for this device. You may obtain the guideline for the preparation of a PMA application, entitled "Premarket Approval (PMA) Manual," from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597.

If you have any questions, please contact Everette T. Beers, Ph.D. at (301) 594-2018.

Sincerely yours,

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic Devices
Office of Device Evaluation
Center for Devices and Radiological Health

DEC 07 1998

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administratic
9200 Corporate Boulevard
Rockville MD 20850

DEC 3 - 1998

Herbert J. Nevyas, M.D.
Nevyas Eye Associates
Delaware Valley Laser Surgery Institute
333 City Line Avenue
Bala Cynwyd, PA 19004

Re: G970088/S13
Sullivan Excimer Laser System (Nevyas Model)
Indications for Use: LASIK (Laser-Assisted In Situ Keratomileusis) to correct myopia of -0.5 to -15 Diopters (D) with up to -7 D of astigmatism for protocol NEV-97-001 Myopia; and, LASIK retreatment to correct myopia and myopic astigmatism of eyes treated with this laser prior to IDE approval
Dated: October 30, 1998
Received: November 2, 1998
HCFA Category: A-2
Next Annual Report Due: August 7, 1999

Dear Dr. Nevyas:

The Food and Drug Administration (FDA) has reviewed the supplement to your investigational device exemptions (IDE) application proposing an accommodation substudy to address multifocality of the LASIK ablation. Your supplement is approved, and you may implement that change at the institution enrolled in your investigation. Your investigation is limited to one institution and 225 subjects (450 eyes): 150 subjects (300 eyes) for low myopia (-0.5 to -6.75 D myopia plus up to -7 D astigmatism); 50 subjects (100 eyes) for high myopia (- 7 to -15 D with up to -7 D astigmatism); and, 25 subjects (50 eyes) for enhancements of subjects treated prior to IDE approval (-0.5 to -15 D myopia with up to -7 D astigmatism).

We would like to point out that FDA approval of your IDE supplement does not imply that this investigation will develop sufficient safety and effectiveness data to assure FDA approval of a premarket approval (PMA) application for this device. You may obtain the guideline for the preparation of a PMA application, entitled "Premarket Approval (PMA) Manual," from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597.

Please be aware that we now believe your proposed mesopic contrast sensitivity study will adequately address deficiency 14 of our letter of October 7, 1997, without the need for a test of the multifocal properties of your ablation, such as your proposed test for change in accommodation. The reason for this is that the contrast sensitivity test may

Although it is not required, you may decide to study the change in accommodation anyway; if you do this study, you should use the same subjects as those enrolled in the contrast sensitivity study. You should also keep in mind that in your proposed test, a subject with a multifocal cornea may accommodate, for several reasons: perhaps the infinity point provides more power than the near point, or perhaps the subject is simply accustomed to accommodating under near viewing conditions. Also, you are only proposing to measure two points (infinity and near). A more informative test would be a depth of focus test under cycloplegic conditions, which would measure acuity at many potential planes of focus. This test would have to be performed with an artificial pupil held close to the eye, because the cycloplegic pupil usually would be larger than the diameter ablated.

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 the best focal plane. It is possible that your proposed mesopic contrast sensitivity study will help resolve some of these concerns. Also, any claims you may wish to assert regarding advantages of multifocality may not be supported by your change in accommodation study.

If you have any questions, please contact Everette T. Beers, Ph.D. at (301) 594-2018.

Sincerely yours,

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic Devices
Office of Device Evaluation
Center for Devices and Radiological Health

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administrati
2098 Gaither Road
Rockville MD 20850

JAN - 7 1999

Herbert J. Nevyas, M.D.
Nevyas Eye Associates
Delaware Valley Laser Surgery Institute
2 Bala Plaza
333 City Avenue
Bala Cynwyd, Pennsylvania 19004

Dear Dr. Nevyas:

During the period of October 6 through November 2, 1998, Nevyas Eye Associates was visited by Mr. Ronald Stokes, an investigator from the Food and Drug Administration's (FDA) Philadelphia District Office. The purpose of that visit was to inspect your activities as a sponsor and clinical investigator of studies of laser assisted in situ keratomileusis (LASIK) for the treatment of myopia, with or without astigmatism, with the Sullivan Excimer Laser, Nevyas model, to determine if they complied with applicable FDA regulations. Excimer lasers are devices as that term is defined in Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

The inspection was conducted under a program designed to ensure that data and information contained in requests for Investigational Device Exemptions (IDE), Premarket Approval Applications (PMA), and Premarket Notifications [510(k)] are scientifically valid and accurate. Another objective of the program is to ensure that human subjects are protected from undue hazard or risk during the course of scientific investigations.

Our review of the inspection report submitted by the district revealed deviations from Title 21, Code of Federal Regulations, (21CFR), Part 812 - Investigational 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. We acknowledge receipt of a November 30 response to the deviations from your consultant, Barbara S. Fant, Pharm. D.

It was noted on the form FDA-483 that two subjects had undergone simultaneous bilateral LASIK surgery prior to IDE approval for bilateral treatment. The response states that the original conditional approval of your IDE, dated 8/7/98, had included simultaneous bilateral surgery but that this approval had been rescinded for all Sullivan laser users on 10/3/97. Enclosed with the response was a copy of a letter to Dr. Everette Beers, Office of Device Evaluation (ODE), from Dr. Richard H. Sterling dated 10/23/97, which notes that two surgeries had been performed under the IDE study but that no additional bilateral procedures would be performed until specific IDE approval had been received. Dr. Beers confirmed that it had been assumed by Dr. Nevyas and other excimer investigators that IDE approval included bilateral

procedures. This had not been intended by ODE and therefore specific requests for this indication were solicited from those who possessed approved IDEs and wished to continue performing bilateral procedures. The letter from Dr. Sterling reflects Dr. Nevyas' adherence to this request. However, according to Mr. Stokes, he was not shown a copy of this letter during his inspection of your Institute.

Another deviation noted was enhancement of a subject prior to approval of the retreatment supplement to the IDE. Dr. Morris Waxler confirmed that the policy of his division was to allow, upon request, enhancement of small numbers of subjects originally treated with an excimer laser prior to IDE approval. This was with the understanding that an official request for an IDE supplement for this indication would follow shortly. The inspection report notes that you stated that you thought the procedure was approved. It does not include mention of verbal permission from Dr. Waxler, as noted in the response.

With regard to issues related to informed consents, the response states that the subject who had not received a copy of the revision of the informed consent as approved by the Institutional Review Board (IRB) for simultaneous bilateral surgery has since been sent the addendum in question. Moreover, your staff has been instructed to assure that the proper informed consent is used and that each consent form contains a properly executed signature and date in both the subject and witness signature areas. These actions should prevent future problems in this area.

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. There is a difference between subjects treated as part of an IDE study and patients treated in the normal course of your practice. It is the responsibility of the clinical investigator to make every effort to assure that the subjects enrolled in a study are aware of the investigational nature of the procedure from the start and the need for specific control of their treatment while they are participants in the study. Treatment of subjects with devices and/or procedures that are not included in the approved IDE are considered protocol violations. The hyperopic enhancement terminates the inclusion of the retreated subjects in the study.

Moreover, according to 21 CFR 812.150(a)(4), an investigator must notify the reviewing IRB of any deviation from the investigational plan in an emergency no later than 5 working days after the emergency occurred. Except in such an emergency, prior approval by the IRB is needed for changes to the protocol.

During the inspection, Mr. Stokes also discussed with you the need to have advertisements related to your IDE study approved by the reviewing IRB. A transcript of a radio advertisement that had aired for several weeks was included with the inspection report (copy enclosed). This advertisement refers to laser vision correction at the Delaware Valley Laser Surgery Institute. According to Mr. Stokes, the only laser at your Bala Cynwyd office used for refractive surgery is your IDE laser. 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.

No further response is necessary. For further information concerning the Bioresearch Monitoring program, please visit our internet homepage at http://www.fda.gov/cdrh/comp/bimo.html. Valuable links to related information are included at this site. If you have any questions, feel free to contact Jean Toth-Allen, Ph.D. at (301) 594-4723, ext. 141.

Sincerely yours,

Viola Sellman

Viola Sellman
Chief
Program Enforcement Branch II
Division of Bioresearch Monitoring
Office of Compliance
Center for Devices and
Radiological Health

Enclosure

FDA 0 0051

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administrat
9200 Corporate Boulevard
Rockville MD 20850

JAN 2 0 1999

Herbert J. Nevyas, M.D.
Nevyas Eye Associates
Delaware Valley Laser Surgery Institute
333 City Line Avenue
Bala Cynwyd, PA 19004

Re: G970088/S15
Sullivan Excimer Laser System (Nevyas Model)
Indications for Use: LASIK (Laser-Assisted In Situ Keratomileusis) to correct myopia of -0.5 to -15 Diopters (D) with up to -7 D of astigmatism for protocol NEV-97-001 Myopia; and, LASIK retreatment to correct myopia and myopic astigmatism of eyes treated with this laser prior to IDE approval
Dated: January 5, 1999
Received: January 6, 1999
HCFA Category: A-2
Next Annual Report Due: August 7, 1999

Dear Dr. Nevyas:

The Food and Drug Administration (FDA) has reviewed the supplement to your investigational device exemptions (IDE) application providing validation data for the contrast sensitivity study. You have corrected the deficiency cited in our September 24, 1998 conditional approval letter. Your application is approved, and you may continue your investigation at the institution enrolled in your investigation where you have obtained institutional review board (IRB) approval. Your investigation is limited to one institution and 1015 subjects (2030 eyes); 990 subjects (1980 eyes) for myopia (- 0.5 to -15 D with up to -7 D astigmatism); and, 25 subjects (50 eyes) for enhancements of subjects treated prior to IDE approval (-0.5 to -15 D myopia with up to -7 D astigmatism).

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.

FDA 0 0052

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 the best focal plane. It is possible that your proposed mesopic contrast sensitivity study will help resolve some of these concerns. Also, any claims you may wish to assert regarding advantages of multifocality may not be supported by your change in accommodation study.

If you have any questions, please contact Everette T. Beers, Ph.D. at (301) 594-2018.

Sincerely yours,

Nancy C. Brogdon for

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic Devices
Office of Device Evaluation
Center for Devices and Radiological Health

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administrati
9200 Corporate Boulevard
Rockville MD 20850

NOV 10 1999

Herbert J. Nevyas, M.D.
Nevyas Eye Associates
Delaware Valley Laser Surgery Institute
333 City Line Avenue
Bala Cynwyd, PA 19004

Re: G970088/S17
Sullivan Excimer Laser System (Nevyas Model)
Indications for Use: LASIK (Laser-Assisted In Situ Keratomileusis) to correct myopia of -0.5 to -15 Diopters (D) with up to -7 D of astigmatism for protocol NEV-97-001 Myopia; and, LASIK retreatment to correct myopia and myopic astigmatism of eyes treated with this laser prior to IDE approval
Dated: October 8, 1999
Received: October 12, 1999
HCFA Category: A-2
Next Annual Report Due: August 7, 2000

Dear Dr. Nevyas:

The Food and Drug Administration (FDA) has reviewed the annual progress report to your investigational device exemptions (IDE) application and has determined that additional information is required. Please address the following questions and concerns:

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

2. Please include an accountability table, similar to the one presented by you in last year's annual report, showing completed visits, missed visits, etc. for each visit time for all eyes. You should account for all eyes treated in the IDE.

This information must be submitted to FDA within 45 days from the date of this letter. It should be identified as an IDE supplement referencing the IDE number above, and must be submitted in triplicate to:

IDE Document Mail Center (HFZ-401)
Center for Devices and Radiological Health
Food and Drug Administration
9200 Corporate Boulevard
Rockville, MD 20850

FDA 0 0054

If you do not provide this information within 45 days from the date of this letter, we may take steps to propose withdrawal of approval of your IDE application.

If you have any questions, please contact Everette T. Beers, Ph.D. at (301) 594-2018.

Sincerely yours,

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic Devices
Office of Device Evaluation
Center for Devices and Radiological Health

FDA 0 0055

FEB 09 2001

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 30 2001

Herbert J. Nevyas, M.D.
Nevyas Eye Associates
Delaware Valley Laser Surgery Institute
333 City Line Avenue
Bala Cynwyd, PA 19004

Re: G970088
Sullivan Excimer Laser System (Nevyas Model)
Indications for Use: LASIK (Laser-Assisted In Situ Keratomileusis) to correct myopia of –0.5 to –15 Dipoters (D) with up to –7 D of astigmatism for protocol NEV-97-001 Myopia; and, LASIK retreatment to correct myopia and myopic astigmatism of eyes treated with this laser prior to IDE approval

Dear Dr. Nevyas:

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). In addition, please provide your annual progress report for the year August 1999 – August 2000.

Please submit your response to FDA's November 10, 1999 letter and your year 2000 annual progress report to FDA within 45 days from the date of this letter. The information should be identified as an IDE supplement referencing the IDE number above, and must be submitted in triplicate to:

IDE Document Mail Center (HFZ-401)
Center for Devices and Radiological Health
Food and Drug Administration
9200 Corporate Boulevard
Rockville, MD 20850

If you do not provide the requested information within 45 days from the date of this letter, we may take steps to propose withdrawal of approval of your IDE application.

FDA 0 0056

If you have any questions, please contact Ms. Deborah Falls at (301) 594-2205.

Sincerely yours,

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and Ear, Nose
and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure
FDA's November 10, 1999 request for additional information regarding annual progress report

FDA 0 0057

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 13 2001

APR 10 2001

Herbert J. Nevyas, M.D.
Nevyas Eye Associates
Delaware Valley Laser Surgery Institute
333 City Line Avenue
Bala Cynwyd, PA 19004

Re: G970088/S18
Sullivan Excimer Laser System (Nevyas Model)
Indications for Use: LASIK (Laser-Assisted In Situ Keratomileusis) to correct myopia of -0.5 to -15 Diopters (D) with up to -7 D of astigmatism for protocol NEV-97-001 Myopia; and, LASIK retreatment to correct myopia and myopic astigmatism of eyes treated with this laser prior to IDE approval
Dated: March 14, 2001
Received: March 16, 2001
Next Annual Report Due: August 7, 2001

Dear Dr. Nevyas:

The Food and Drug Administration (FDA) has reviewed the annual progress report to your investigational device exemptions (IDE) application and has determined that additional information is required.

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

1. You have stated that, for the safety and efficacy analyses, the "N" used as the denominator when calculating percentages was the actual number of patients completing each visit. The "N" should be the number of eyes that completed the particular evaluation being analyzed at that visit. For example, if a subject, who had bilateral treatment, was available for analysis at the 1-month follow-up visit, but did not undergo manifest refraction, this subject's 2 eyes would not be included in the "N" (or the "n", numerator of the percentage calculation) for the BSCVA analysis. Please adjust the tables accordingly, if necessary.

2. The only protocol deviations reported were that "some" visits were completed outside the visit windows. Visits falling outside the visit window should not be included in the analyses at that particular visit, but should be analyzed separately. Please revise your tables accordingly including the accountability tables.

FDA 0 0058

3. Please provide stability analyses and indicate the point of stability for each indication (see enclosed tables).

4. You reported the percentage of eyes losing more than 2 lines of BSCVA. This should

5. Please provide narratives for the reported adverse events/complications to further elaborate these events and their outcomes.

6. Please provide a summary of contrast sensitivity results.

7. 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.

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. Data from all eyes treated prior to the adaptation of the new centration technique may be analyzed separately from the main PMA cohort, but must be submitted as supportive evidence.

This information must be submitted to FDA within 45 days from the date of this letter. It should be identified as an IDE supplement referencing the IDE number above, and must be submitted in triplicate to:

IDE Document Mail Center (HFZ-401)
Center for Devices and Radiological Health
Food and Drug Administration
9200 Corporate Boulevard
Rockville, MD 20850

If you do not provide this information within 45 days from the date of this letter, we may take steps to propose withdrawal of approval of your IDE application.

FDA 0 0059

If you have any questions, please contact Everette T. Beers, Ph.D. at (301) 594-2018.

Sincerely yours,

Nancy C Brogdon for

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure
Data Tables – October 26, 1998 Version

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administratio
9200 Corporate Boulevard
Rockville MD 20850

JUL 25 2001

Herbert J. Nevyas, M.D.
Nevyas Eye Associates
Delaware Valley Laser Surgery Institute
333 City Line Avenue
Bala Cynwyd, PA 19004

Re: G970088/S20
Sullivan Excimer Laser System (Nevyas Model)
Dated: June 21, 2001
Received: June 25, 2001
Next Annual Report Due: August 7, 2001

Dear Dr. Nevyas:

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:

1. You have stated that subjects will be evaluated preoperatively and 1 day, 1 week, and 1, 3, and 6 months post-LASIK, and that a final exam will be conducted at least 3 months after the time when refractive stability is achieved. For new indications, where the time point of stability is not established, we recommend 24 months of follow-up. We consider all indications using the new, spherical ablation algorithm to be "new" indications. Please revise your protocol, case report forms, and consent form accordingly, or justify not doing so. Please add evaluations for each study eye at 9, 18, and 24 months postoperatively regardless of the individual subjects' postoperative refractive stability. You may request to modify your protocol if the preliminary data indicate earlier stability of the cohort. Please note that the point of stability may differ for different refractive indications, e.g., low spherical myopia only, high spherical myopia only, low myopia with astigmatism, high myopia with astigmatism, spherical hyperopia, and hyperopia with astigmatism.

2. You have identified target values at the "mean time of stability" and you have defined stability as "two manifest refraction spherical equivalent (MRSE) measurements taken at two consecutive visits that are at least 2 to 3 months apart that are within 1.0 D of each other". The FDA normally evaluates target values at the point of stability defined as the time point when 95% of the eyes have a change of $\leq$ 1D of MRSE between 2 refractions performed at least 3 months apart. Please revise your protocol in order to be consistent with the FDA's definitions.

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.

4. You have indicated that pupil size measurements will be performed in dim lighting conditions, ~2 lux. However, this is closer to photopic than mesopic conditions (~0.1 lux) that are required for appropriate inclusion of subjects in the study. Please specify in your protocol how the pupil size measurement will be obtained, as requested above, and revise the lighting conditions under which this measurement will be obtained to assure that the measurement will be performed under mesopic conditions. We recommend dark adaptation for 10 minutes prior to the measurement and the use of an infrared pupillometer for consistency of the measurement.

5. Section 8.7 of each protocol states that the manufacturer's recommended settings are provided in Attachment D, and that the optical zone size (transition zone = 7.5 mm or 9.0 mm) will be selected by the investigator in accordance with the manufacturer's recommendations. Attachment D was not provided, however, and the previous statement implies that the optical zone size may be varied within each protocol. Please provide the optical zone and corresponding transition zone sizes for each of the indications - spherical myopia, myopic astigmatism, spherical hyperopia, and hyperopic astigmatism. Please note that we do not recommend varying the optical zone and transition zone according to an algorithm. However, if you choose to utilize varying optical zones, please provide adequate justification and the algorithm for determining zone size. In this case, you are reminded that outcomes must be stratified by optical zone and, possibly, transition zone.

6. The refractive inclusion criteria for Protocol NEV-01-002 (Myopia/Myopic Astigmatism) indicate that the uncorrected refractive error must consist of spherical myopia (-0.5 D to -16.0 D) or myopic astigmatism (-0.50 D to -16.0 D MRSE; cylinder -0.5 D to -6.0 D) for inclusion in the study. You also noted that the minimum allowable cylinder treatment is -0.5 D and that eyes with cylinder between 0.0 D and < 0.5 D may be enrolled in the study, but the cylinder cannot be treated. The refractive inclusion criteria for Protocol NEV-97-003 (Hyperopia/Hyperopic Astigmatism) indicate that the uncorrected refractive error consists of spherical hyperopia (+0.50 to +6.00D) or hyperopic astigmatism (+0.50 to +6.00 D MRSE; cylinder +0.50 to +4.00 D) for inclusion in the study. You also noted that the minimum allowable cylinder treatment is 0.5 D and that eyes with cylinder between 0.0 D and < 0.5 D may be enrolled in the study, but the cylinder cannot be treated. It has been FDA's experience that there is more variability in refractive outcomes with lower corrections. Therefore, please justify the lower limits of your refractive inclusion criteria by providing a scientific argument for why you think you will be able to accurately treat and measure the outcomes at the lower limits of the refractive ranges you have chosen. Otherwise, please use 0.75 D as your lower unit for sphere and cylinder.

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.

8. Please add an inclusion criterion for uncorrected visual acuity (UCVA), e.g., UCVA of worse than 20/40.

9. Protocol NEV-01-002 (Myopia/Myopic Astigmatism) states that subjects must have a stable manifest refraction defined as $\leq$ 0.5D change in sphere or cylinder during the year prior to the screening examination for inclusion in the study. Please revise your protocol to indicate that this inclusion criterion applies to subjects with high myopia, ($\geq$ 7 D MRSE). Please add that subjects with low myopia (MRSE < 7 D) must have a stable correction ($\pm$ 0.5 D), as determined by MRSE, for a minimum of 12 months prior to surgery.

10. Similarly, Protocol NEV-97-003 (Hyperopia/Hyperopic Astigmatism) states that subjects must have a stable manifest refraction defined as $\leq$ 0.5D change in sphere or cylinder during the year prior to the screening examination for inclusion in the study. Please revise your protocol to indicate that subjects must have a stable correction ($\pm$ 0.5 D), as determined by MRSE, for a minimum of 12 months prior to surgery.

11. Section 7.2 of your protocol states that subjects wearing hard contact lenses must have 2 refractions and central K readings taken at least 1 week apart that are within 0.5 D for both sphere and cylinder before undergoing LASIK. Please revise this inclusion criterion so that it applies not just to hard contact lens wearers, but all contact lens wearers, and so that it is consistent with the revised inclusion criterion regarding stability referred to above.

12. Your protocol states that subjects who have pupils (measured in dim illumination) that are too large compared to the intended optic zone should be excluded from the study. Please revise your protocol to indicate that subjects with mesopic pupil measurements $\geq$ the planned optic zone should be excluded from the study.

13. Please add axial length measurement to the baseline eye examination.

14. The postop Day 1 (1 to 3 days postop) and Week 1 (5 to 12 days postop) visit windows you have proposed are too long. We recommend the following visit windows - Day 1 (24-36 hours) and Week 1 (5-9 days). Please revise Appendix B accordingly, or justify not doing so.

15. Section 8.4, "Follow-Up Visits", is inconsistent with Appendix A: Study Flow Chart and the Notes for the Examination Schedule. For example, Section 8.4 of Protocol

NEV-01-002 (Myopia/Myopic Astigmatism) states that UCVA at near will be performed at Month 3 and the Final Exam. However, the Study Flow Chart in Appendix A indicates that UCVA at near should only be performed at the screening visit. As another example, Section 8.4 of Protocol NEV-97-003 (Hyperopia/Hyperopic Astigmatism) states that UCVA at near will be performed at Month 3 and the Final Exam. However, the Study Flow Chart in Appendix A indicates that UCVA at near should be performed at the screening visit and at Month 3. Please resolve all discrepancies between the text in Section 8.4, the Study Flow Chart, and the footnotes under Notes for the Examination Schedule.

16. You have listed late onset of haze beyond 6 months with loss of 2 lines (10 letters) or more BSCVA as one adverse event, and haze beyond 6 months with loss of $\geq$ 2 lines of BSCVA as another adverse event. Please delete the first version of this haze adverse event from your protocol.

17. You have listed a decrease in BSCVA of more than 10 letters not due to irregular astigmatism as shown by hard contact lens refraction at 6 months or later as a possible adverse event. You have also listed a decrease in BSCVA of $\geq$ 2 lines at 3 months or later as another possible adverse event. Please delete the first version of this decreased BSCVA adverse event from your protocol.

18. Please add a statement to your consent form indicating that there are lasers approved for LASIK for the treatment of myopia with and without astigmatism and hyperopia with and without astigmatism.

19. As part of the discussion of alternatives in your consent form, please discuss intra-corneal rings for the treatment of myopia and thermal keratoplasty for the treatment of hyperopia.

20. The Voluntary Participation section of the consent form states that the study doctor can stop the subject's participation at any time if the subject fails to follow directions for participating in the study, or if it is discovered that the subject does not meet the study requirements. Since this is a device investigation, non-compliance with the study procedures is not an acceptable reason for the subject's discontinuation. In addition, if it is discovered after surgery that a subject did not meet the study requirements, a protocol violation should be noted, but the subject should not be discontinued from the study. Please revise the consent form to clarify these points.

21. The Conclusion section of the consent form states, "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

been studied by the FDA, and the FDA does not regulate LASIK, only the devices used for the procedure.

22. Question 8 of the Informed Consent Quiz states, "TRUE OR FALSE: There is a good chance that my eyes will regress to the refractive error as before the surgery," and the Correct Answers and Explanation states, "FALSE There is practically no chance that your vision will regress completely." Since this is the subject of your IDE study, please remove this question from your consent form.

23. Please submit the intra-operative/day of surgery case report form for review.

24. Please be advised that until preliminary safety, efficacy, and stability are demonstrated in a sufficient number of eyes, we cannot allow fellow eye treatment or re-treatment. In addition, subject enrollment should occur in stages in an IDE study for a new technology, new refractive laser device, or a new indication. FDA will evaluate the subject data from each stage prior to expansion of the study. You may request a protocol modification to include fellow eye treatment, re-treatment, and an increase in the number of subjects by submitting data demonstrating satisfactory stability, safety and efficacy. Please revise your protocol and informed consent document accordingly. We recommend for the early subjects to be contact-lens tolerant in the fellow eye. These subjects should be advised that six or more months may elapse before fellow-eye treatment is allowed.

25. Please confirm that subjects with mixed astigmatism will not be enrolled into either protocol.

26. Please verify that there will only be 2 investigators involved in this study.

27. Please provide your agreement that all co-managing doctors that collect data on the study subjects will be considered sub-investigators, and, therefore, they will need to follow the same SOP's under the protocol and sign the investigator's agreement prior to their participation in the study.

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.

Please respond to the following engineering concerns:

29. In Section 2.2 (Page 8-9), the total cumulative number of pulses (shown in Figure 2.2-1) for each area in a selected 1.33 mm zone does not match your narrative. Based on your description, the pulses are delivered to a diamond shaped area (not a slot area). It

appears that area of square 8 receives the total 4 pulses at each axis; area 7 receives 3 (4 - 1) pulses; area 6 receives 2 (4 - 2) pulses; and area 5 receives 1 (4 - 3) pulse. However, in Figure 2.2-1, you marked that areas (8 - 5) along the axis 0° receive all of 4 pulses at axis of 0° and areas (8 - 5) along the axis 90° receive all of 4 pulses at axis of 90°. Please explain this discrepancy.

31. With respect to the profiles of your ablated PMMA samples:

a. The PMMA ablations for the spherical myopia (Fig 1-3), appear to have a "hump" in the bottom. Please explain the causes and discuss the potential impact of this "hump" on safety and effectiveness. In addition, your PMMA ablation curves did not include theoretical curves. Please provide plots of PMMA ablations versus the theoretical curves.

b. The PMMA ablations for the astigmatism (Fig 7-15) appear to be notably asymmetric. In particular, the asymmetry seems to be about 25% of the ablation depth in the maximal astigmatism as shown in Fig 9. Also, since you stated that (in Table 3-2) the signal to noise ratio was too low to obtain meaningful data at –0.5 D cylinder, you should improve the quality of the laser beam to enhance the signal to noise ratio. This might improve the quality of your astigmatic ablations. After improving the quality of your laser beam, please provide PMMA ablations for the astigmatism profiles to include sections through both axes, and plot these ablations versus the theoretical curves.

32. With respect to the software, please provide the following information:

a. Software Description: description and flowchart of the software lifecycle of the device, a flow diagram and narrative about the function of the software and about how the software interacts with the hardware.

b. Software Requirements Specifications (SRS): the Software Requirements Specification document, which clearly documented their functional, performance, interface, design and development requirements.

c. Validation (including verification and testing): an acceptable description of the systematic process of life cycle activities, including analysis, evaluation, assurance and testing of the software, and supporting documentation. This included a description of the activities and protocols at the unit, integration and system level, including pass/fail criteria, test reports, summaries and tests results.

d. Certification: if the software design, development and maintenance system have been certified to an international or national standard, specify to which standard and provide the name of the organization that performed the certification.

e. Revision Level History: the revision history log, documenting all major changes to the software during its development cycle and a description of the version numbers and dates.

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. We believe that we have considered the least burdensome approach to resolving these issues. If, however, you believe that information is being requested that is not relevant to the regulatory decision or that there is a less burdensome way to resolve the issues, you should follow the procedures outlined in the "A Suggested Approach to Resolving Least Burdensome Issues" document. It is available on our Center webpage at: http://www.fda.gov/cdrh/modact/leastburdensome.html

If you submit information correcting the deficiencies, FDA will reevaluate the proposed change in the investigational plan. Please submit revised versions of the protocols, consent form, and any revised case report forms indicating deletions with strikethroughs and additions with underlines.

This information should be identified as an IDE supplement referencing the IDE number above, and must be submitted in triplicate to:

IDE Document Mail Center (HFZ-401)
Center for Devices and Radiological Health
Food and Drug Administration
9200 Corporate Boulevard
Rockville, MD 20850

Alternatively, you may request a regulatory hearing regarding the disapproval of your IDE supplement. The enclosure "Procedures to Request a Regulatory Hearing" describes how to submit such a request. The procedures governing a regulatory hearing are described in the regulations at 21 CFR Part 16.

Please take into consideration the following issues related to any future PMA submissions when revising your protocol:

33. The protocol indicates that the subject questionnaire will be administered 3 and 6 months postoperatively and at the final exam with optional administration at the other visits. Please be advised that subject questionnaire data are expected at the point of stability. We recommend you remove the option for administration of the questionnaire "at other visits" and consider adding this as a mandatory evaluation to other follow-up visits, if there is the possibility that the cohort (or a subgroup) may reach stability after 6 months.

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. Therefore, if you intend to seek approval for each indication you have proposed in the submission, you will need data from ~125 eyes in each of the following groups - the low spherical myopia only group, the high spherical myopia only group, the low myopia with astigmatism group, the high myopia with astigmatism group, the spherical hyperopia only group, and the hyperopia with astigmatism group.

35. Please be aware that if a subject moves and is, therefore, no longer followed in the study, the subject is considered lost-to-follow-up for purposes of reporting accountability.

If you have any questions, please contact Alfred Montgomery DVM at (301) 594-2080.

Sincerely yours,

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure
(1) Procedures to Request a Regulatory Hearing

FDA 0 0073

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Herbert J. Nevyas, M.D.
Delaware Valley Laser Surgery Institute
333 City Line Avenue
Bala Cynwyd, PA 19004

AUG 16 2001

Re: G970088/S22
Nevyas Excimer Laser
Dated: July 20, 2001
Received: July 23, 2001
Annual Report Due: August 7, 2001 (overdue)

Dear Dr. Nevyas:

The Food and Drug Administration (FDA) has reviewed the supplement to your investigational device exemptions (IDE) application proposing the validation for Appollo Software. 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. Please provide a step-by-step description, from the very first pulse to the last pulse, of how the ablation pattern(s) to be used in this study is(are) to be created by the device. This description should include specific values for the starting size for the iris, starting position for slot, the amount to incremental change for iris or slot, etc.

2. The provided Hazard Analysis and Test Data appear to be limited to the user-interface function of the software. Given all the functions of the software, please identify those that are either safety critical or safety-related (see the Checklist of Information Usually Submitted in an IDE for Refractive Surgery Lasers, section 3.4.1.3 D, available at http://www.fda.gov/cdrh/ode/2093.html), and discuss how those safety functions were validated.

3. The Revision History Log is only up to version 3.22. Please update it to include all revisions up to version 3.66, which appears to be the latest version for the software.

4. The software allows the user to set 10 preferences such as fluence count & size; nitrogen on/off delay(s); laser frequency; wipe alert options, etc., and for manual positioning of the aperture doors and angle, and selection of iris size. Please specify which, among the selectable options in software, are selected for the study.

5. The naming convention for the software is confusing and inconsistent with the typical software practice. Typically, the higher software version would include everything in the lower version, as well as some additional features. Therefore, if Apollo version 3.66 were installed in the machine, there should be no need to install Apollo version 3.5. If 3.5 and 3.66 contain two distinct and separate routines, then different names should be given to them and their versions should each be 1.0.

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. We believe that we have considered the least burdensome approach to resolving these issues. If, however, you believe that information is being requested that is not relevant to the regulatory decision or that there is a less burdensome way to resolve the issues, you should follow the procedures outlined in the "A Suggested Approach to Resolving Least Burdensome Issues" document. It is available on our Center webpage at: http://www.fda.gov/cdrh/modact/leastburdensome.html

If you submit information correcting the deficiencies, FDA will reevaluate the proposed change in the investigational plan. This information should be identified as an IDE supplement referencing the IDE number above, and must be submitted in triplicate to:

IDE Document Mail Center (HFZ-401)
Center for Devices and Radiological Health
Food and Drug Administration
9200 Corporate Boulevard
Rockville, MD 20850

Alternatively, you may request a regulatory hearing regarding the disapproval of your IDE supplement. The enclosure "Procedures to Request a Regulatory Hearing" describes how to submit such a request. The procedures governing a regulatory hearing are described in the regulations at 21 CFR Part 16.

If you have any questions, please contact Alfred Montgomery, DVM at (301) 594-2080.

Sincerely yours,

for A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure:
Procedures to Request a Regulatory Hearing

FDA 0 0076

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 26 2002

Herbert J. Nevyas, M.D.
Nevyas Eye Associates
Delaware Valley Laser Surgery Institute
333 City Line Avenue
Bala Cynwyd, PA 19004

Re: G970088/S25
Sullivan Excimer Laser System (Nevyas Model)
Indications for Use: LASIK (Laser-Assisted In Situ Keratomileusis) to correct myopia of -0.5 to -15 Diopters (D) with up to -7 D of astigmatism for protocol NEV-97-001 Myopia; and, LASIK retreatment to correct myopia and myopic astigmatism of eyes treated with this laser prior to IDE approval
Dated: March 26, 2002
Received: March 27, 2002
Next Annual Report Due: August 7, 2002

Dear Dr. Nevyas:

The Food and Drug Administration (FDA) has reviewed the additional information for your annual progress report to your investigational device exemptions (IDE) application and has determined that additional information is required.

Please address the following questions and concerns with regard to this submission:

1. You must still provide responses to deficiencies 1, 2, 3, and 5 from our letter of February 6, 2002.

2. You did not provide the requested information in your response to deficiency 4.

   a. For the eye with the central, corneal infiltrate noted at the 1-month visit, please report the eye's preoperative BSCVA, how the infiltrate was managed (i.e., cultures, antibiotics administered, etc.), when the infiltrate resolved, and the final BSCVA.

   b. In addition, you stated, "The observation was omitted from the 2001 Annual Report because the adverse event listing is 'corneal infiltrate or ulcer at 1 month or later' and the observation actually occurred earlier than 1 month postoperatively (although the infiltrate was noted at the 1-month visit, 25 days postoperatively)." We would like to point out that the FDA interprets "1 month or later" to mean within the 1-month visit window or later. This is true as well for all other time point references made in the protocol. Please keep this in mind when preparing all other future submissions to the FDA.

3. Although you have reported the number of eyes with unintended over-corrections > 2 D at each time point starting at 3 months in response to deficiency 6, it is not clear whether these reports represent different eyes at each visit or whether some of the reports are for the same eye. Please clarify.

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.

Please note: In response to a question you asked previously by telephone, eyes that have been enhanced are considered discontinued at the point of enhancement (retreatment). These are then treated the same as the monovision subjects; that is, they are accounted for and analyzed separately. You should not enter subjects into the study that you know you are going to undercorrect or enhance.

This information must be submitted to FDA within 45 days from the date of this letter. It should be identified as an IDE supplement referencing the IDE number above, and must be submitted in triplicate to:

IDE Document Mail Center (HFZ-401)
Center for Devices and Radiological Health
Food and Drug Administration
9200 Corporate Boulevard
Rockville, MD 20850

If you do not provide this information within 45 days from the date of this letter, we may take steps to propose withdrawal of approval of your IDE application.

If you have any questions, please contact Everette T. Beers, Ph.D. at (301) 594-2018.

Sincerely yours,

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Morris Waxler, Ph.D.
Food and Drug Administration
Center for Devices and Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ401)
9200 Corporate Blvd.
Rockville, MD 20850

IDE: G970088

To Dr. Waxler:

On July 28, 1997, FDA requested additional information regarding my investigational device exemption (IDE) application for a Sullivan excimer laser system (which I refer to in my IDE application as Nevyas Excimer Laser and hereafter refer to as "the laser") for use in refractive eye surgery. This letter responds to FDA's request for additional information.

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.

Executed on 8/6, 1997.

Sincerely,

FDA C083

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 6 2002

Herbert J. Nevyas, M.D.
Nevyas Eye Associates
Delaware Valley Laser Surgery Institute
333 City Line Avenue
Bala Cynwyd, PA 19004

Re: G970088/S24
Sullivan Excimer Laser System (Nevyas Model)
Indications for Use: LASIK (Laser-Assisted In Situ Keratomileusis) to correct myopia of -0.5 to -15 Diopters (D) with up to -7 D of astigmatism for protocol NEV-97-001 Myopia; and, LASIK retreatment to correct myopia and myopic astigmatism of eyes treated with this laser prior to IDE approval
Dated: January 5, 2002
Received: January 8, 2002
Next Annual Report Due: August 7, 2002

Dear Dr. Nevyas:

The Food and Drug Administration (FDA) has reviewed the annual progress report to your investigational device exemptions (IDE) application and has determined that additional information is required.

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:

1. When reporting protocol deviations, you indicated that some subjects had study visits that were late. For each time point, please clarify how many eyes had visits that fell outside of the visit window. Please clarify how far outside of the visit window each of these visits fell. Visits falling outside the visit window should not be included in the analyses at that particular visit, but should be analyzed separately. Please revise your tables accordingly including the accountability tables.

2. For each eye that experienced a loss of 2 or more lines of BSCVA at 6 months or later postoperatively and for each eye that had BSCVA worse than 20/40 at 6 months or later, please provide a dataline listing and an explanation for the vision loss or vision. Please include a narrative for each case discussing any other visual or non-visual symptoms, the management, and the outcome. Please group this information according to the 4 indications for treatment in this protocol.

FDA 0 0167

3. Please provide narratives to further elaborate on each case reported as a complication, including the management and outcome, for eyes not included in the narratives above. Please group this information according to the 4 indications for treatment.

4. The adverse event previously reported in the last annual report, 1 case of a corneal infiltrate or ulcer at 1 month postoperatively, was not included in the tabulation of adverse events in this report. Please elaborate on this adverse event including the subject's preoperative visual status, management, and outcome.

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.

Please address the following additional deficiencies related to the annual report:

6. Please report the rate of unintended overcorrections > 2 D at 3 months or later, a key safety variable.

7. Although page 38 of this annual report indicates that 188 eyes were enrolled in the contrast sensitivity substudy, Substudy NEV-98-002, page 4 states that a total of 184 eyes of 113 subjects have been enrolled in this substudy – 92 low myopia subjects and 21 high myopia subjects. Please resolve this apparent discrepancy.

8. Accountability is extremely poor. Please describe how you intend to improve accountability by assuring proper follow-up of subjects according to your protocol during your ongoing IDE study. Please be advised that aside from being a serious PMA concern, continued, improper follow-up of subjects may be reason for withdrawal of approval of an IDE study by the FDA.

9. You indicated to FDA, through your consultant Dr. Fant, that you are no longer enrolling subjects. However, it appears that you enrolled subjects up to at least December 19, 2001. As you have been advised previously, you are required to submit monthly accountability reports for each subject treated; these reports should include the investigator, the patient identifier, the eye treated, the date treated and the treatment performed.
   a. Please provide these monthly reports beginning with patients treated in January, 2002.
   b. The last monthly report we have on file is for January 1998. Please provide an accountability table for all eyes treated since January 20, 1998, in the format described in a., above.
   c. If you have ceased enrollment, please submit a request to FDA to cease enrollment. If this is the case, you still need to provide the information requested in b. above up to the date of cessation of enrollment.

You should also give serious consideration to the following items which are considered important for the analysis of your data for the purposes of determining safety and effectiveness for a future PMA application.

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. However, the eyes treated for high myopic astigmatism (high astigmatic group) appear to remain unstable throughout the follow-up period. If PMA approval were requested for all of these indications in one submission, a decision regarding approval would be significantly affected by the inability to confirm stability at the same time point for each of the indications under consideration.

2. As previously stated in FDA's letter of April 10, 2001, 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. Data from all eyes treated prior to the adaptation of the new centration technique may be analyzed separately from the main PMA cohort, but must be submitted as supportive evidence.

3. As indicated above, your follow-up accountability is very low. Seventy-five to 80% of total eyes treated should have reached the point of stability and, of those, about 80% should have been seen and accounted for at the stability time point.

This information must be submitted to FDA within 45 days from the date of this letter. It should be identified as an IDE supplement referencing the IDE number above, and must be submitted in triplicate to:

IDE Document Mail Center (HFZ-401)
Center for Devices and Radiological Health
Food and Drug Administration
9200 Corporate Boulevard
Rockville, MD 20850

If you do not provide this information within 45 days from the date of this letter, we may take steps to propose withdrawal of approval of your IDE application.

If you have any questions, please contact Everette T. Beers, Ph.D. at (301) 594-2018.

Sincerely yours,

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Exhibit B

Nevyas Eye Associates / Delaware Valley Laser Surgery Institute
Ambulatory Surgery Center

rbert J. Nevyas, M.D.
taract, Refractive, and
orneal Surgery

oann Y. Nevyas, M.D.
'taract & Glaucoma Surgery
nd Therapy

nita Nevyas-Wallace, M.D.
taract, Refractive, and
rneal Surgery

a B. Wallace, M.D.
phthalmic Plastic &
constructive Surgery

lward A. Deglin, M.D.
reo-Retinal Disease & Surgery

.. Stein, M.D.
ucoma, Retinal Disease,
dical & Surgical Ophthalmology

in M. DeVaro, M.D.
diatric Ophthalmology
dor Motility &
ro-Ophthalmology

Delaware Valley Laser Surgery Institute
Institutional Review Board
2 Bala Plaza
Bala-Cynwyd, Pa. 19004

Dr. Herbert Nevyas
2 Bala Plaza
Bala-Cynwyd, Pa. 19004

Dear Dr. Nevyas,

On June 17, 1996 the Institutional Review Board of the Delaware Valley Laser Surgery Institute met and reviewed the following protocols submitted for Laser Assisted Intrastromal Keratomileusis:

myopia -1.00 to -24.00 without astigmatism and no previous eye surgery

The protocol was approved and is to be implemented as stated in the protocol itself. The protocol will expire on June 17, 1997 at which time it can be submitted for re-approval.

Sincerely,

Chairman,
Delaware Valley Laser Surgery Institute
Institutional Review Board

000001

EXHIBIT
H. Nevyas-1
5-6-05

Nevyas Eye Associates / Delaware Valley Laser Surgery Institute
Ambulatory Surgery Center

Herbert J. Nevyas, M.D.
Cataract, Refractive, and Corneal Surgery

Joann Y. Nevyas, M.D.
Cataract & Glaucoma Surgery and Therapy

Anita Nevyas-Wallace, M.D.
Cataract, Refractive, and Corneal Surgery

Ira B. Wallace, M.D.
Ophthalmic Plastic & Reconstructive Surgery

Edward A. Deglin, M.D.
Vitreo-retinal Disease & Surgery

[illegible]ell E. Stein, M.D.
Glaucoma, Retinal Disease, Medical & Surgical Ophthalmology

John M. DeVaro, M.D.
Pediatric Ophthalmology Ocular Motility & Neuro-Ophthalmology

Delaware Valley Laser Surgery Institute
Institutional Review Board
2 Bala Plaza
Bala-Cynwyd, Pa. 19004

Dr. Herbert Nevyas
2 Bala Plaza
Bala-Cynwyd, Pa. 19004

Dear Dr. Nevyas,

On July 12, 1996 the Institutional Review Board of the Delaware Valley Laser Surgery Institute met and reviewed the following protocols submitted for Laser Assisted Intrastromal Keratomileusis:

1. Hyperopia +0.75 diopter to +10.00diopters with less than -1.00 diopters of astigmatism

2. Astigmatism -1.00 diopters to -12.00 diopters

3. Astigmatism -1.00 diopters to -12.00 diopters, history of previous eye surgery

4. myopia -1.00 diopters to -24.00 diopters with less than -1.00 diopter astigmatism , history of previous eye surgery

The protocol was approved and is to be implemented as stated in the protocol itself. The protocol will expire on July 12, 1997 at which time it can be submitted for re-approval.

Sincerely,

Chairman,
Delaware Valley Laser Surgery Institute
Institutional Review Board

000002

May-05-99 12:05P

MOJO INTERACTIVE

MEMO

May 5, 1999

Nevyas Eye Associates
Bala Cynwyd, Pa. 19004

Dear Dr. Sterling:

Thank you for allowing us at Mojo Interactive the opportunity to present to you the following proposal, to work with you in the redesign of your website, www.nevyas.com. I will lay out to you the all-inclusive package as you requested and notate any changes or amendments. Your site will include:

*Graphical design & navigational layout	*Project profiler & site checklist
*Secure preview/project site to monitor	*Domain name registration
*Server set-up	*Three months hosting
*Unlimited e-mail forwarding	*Link to existing e-mail address

This proposal will include up to 15 pages of content with 15 scanned images, which we call our "Advanced Cyber Package". With this package, any additional pages we would need to design would be at $60.00 per page. We will submit your site to the top 400 quarterly search engines and furnish you with 3 months of Log Reports. I will extend the hosting for an additional 12 months for $360.00 and the log report for $10.00 per month, $120.00 per year. Normal host rates run from $45-60.00 per month.

I will refer to the paperwork that you faxed to me at this point to complete this proposal for you. Bullet point 1, included. Point 2 included. Point 3: on-line video will be $100.00 per actual live minutes one time charge and $100.00 per minute for point 8. It will also add an additional hosting fee of $25.00 per month. Point 4, e-mail, included. Point 7, banners we can create for $200.00 per tile. Points 5 & 6: As I mentioned, the zip code search would work similar to the search we have on LocateADoc.com. These costs will include $350.00 to program the search, $1,000.00 for the database creation and $250.00 programming if you supply us with the database. If we have to input the information it would be billed at an hourly rate.

The cost to complete this project for you as detailed above, excluding Bullet points 3,5,6,7 and 8 will be $2,515.00. With the additional hosting and log reports, the total cost would be $2,995.00, with an estimated completion time of four to six weeks. MOJO INTERACTIVE requires a 50% deposit ($1,497.50) to begin your redesign. An additional 25% is due at the time you have agreed to all modifications, with the remaining 25% due at the time that your web site goes live.

I thank you again for allowing us at MOJO INTERACTIVE, to make this proposal to you. I look forward to working with you to redesign the Nevyas Eye web site. Please call toll free if you have any questions to 1-877-665-6798 x-102.

Sincerely,

Blaine A. Roseberry
Director, Sales & Marketing

MOJO

AGREEMENT

MOJO INTERACTIVE

INTERNET BANNER ADVERTISING AGREEMENT

This Agreement is made and entered into this 23RD day of APRIL, 1999 between Mojo Interactive Corporation ("Mojo"), having its principal place of business at 7255 Estapona Circle, Fern Park, Florida 32730.
and NEVIAS EYE ASSOCIATES ("Advertiser"), whose address is
2 BALA PLAZA BALA CYNWYD, PA 19004.

Whereas, Mojo provides on its Internet Web site, http://www.locateadoc.com, a section which provides a listing of doctors on a state-by-state basis ("Locate A Doctor"). Mojo also maintains and operates a portion of the www.locateadoc.com site which provides medical related information for patients.

Whereas, Mojo agrees to lease space on its Locate A Doctor section of its Internet Web site to Advertiser for it to advertise its practices services or expertise.

Whereas, Advertiser desires to lease space on Mojo's Internet Web site during the term of this Agreement and Mojo is willing to publish and display this advertisement upon the terms and conditions provided in this Agreement.

Now, therefore, the parties mutually agree as follows:

1. This Agreement shall commence on the date of execution and shall continue for a period of 1 YEAR. (the "Initial Term"). The Advertiser shall have the option to renew this Agreement on a month-to-month basis or on such other terms as agreed to by the Advertiser and Mojo after the expiration of the Initial term of the Agreement, provided that the Advertiser is not and has not been in default. The Advertiser shall be deemed to have automatically elected to renew this Agreement on a month-to-month basis after the Initial Term unless the Advertiser provides written notice to Mojo not less than fifteen (15) days prior to the expiration of the Initial Term of this Agreement of its intention not to exercise the renewal option. The Advertisers may cancel this Agreement at any time during the renewal option period upon fifteen (15) days prior written notice to Mojo.

2. Advertiser agrees to lease space on Mojo's Web site page for 12. number of advertisements at a price of $2,500 PP ~~per advertisement~~.

3. Advertiser is entitled to publish and display an advertisement regarding its services or expertise on the Locate A Doctor section of Mojo's Internet Web site. The advertisement will be approximately 1 1/2" BY 1 1/4" (120w X 90h pixels, less than 12 Kbytes). Position of the advertisement is solely within the discretion of Mojo.

4. Advertiser is also entitled to display a hyper-link to its Web site or an e-mail address in its advertisement (please specify WEB SITE).

5. Advertiser may not resell, assign or transfer any of its rights hereunder, and any attempt to resell, assign or transfer such rights shall result in immediate termination of this Agreement, without liability to Mojo.

6. In the event that Mojo fails to publish or display an advertisement in accordance with this Agreement (or in the event of any failure, technical or otherwise), the sole liability of Mojo to the Advertiser shall be limited to either a refund of the advertising fee or placement of the advertisement at a later time in a comparable position. In no event shall Mojo be responsible for any consequential, special, lost profits, or other damages arising from the failure to timely publish any advertisement in accordance with this Agreement.

7. Advertiser warrants that it has the right to publish the contents of the advertisement, and that the advertisement does not violate any parties intellectual property rights or proprietary rights. In consideration of such publication, Advertiser agrees to indemnify and hold Mojo harmless against any and all expenses and losses of any kind (including reasonable attorneys fees) incurred to Mojo in connection with any claim arising out of the publication of the advertisement (including without limitation, any claim of trademark or copyright infringement, libel, defamation, breach of confidentiality, false or deceptive advertising or sales practices) and/or any material of Advertiser to which users can link through the advertisements.

8. Mojo reserves the right to reject or cancel any advertisement at any time.

9. This Agreement shall be governed by and construed in accordance with the laws of the State of Florida, may only be amended by written agreement, and constitutes the complete understanding between the parties

10. During the Initial Term, the Advertiser may cancel this Agreement, but the Advertiser shall be responsible for the full payment of the fee set forth in paragraph 2. After the expiration of the Initial Term, and during the exercise of any renewal option, the Advertiser may cancel this Agreement at any time upon fifteen (15) days prior written notice to Mojo, and the Advertiser shall be responsible for the payment of Mojo's fees through the date of termination.

Advertiser

X_____

Title:

Mojo Interactive

_____

Title:

Ad Copy

Text: WEB SITE (Nevyas@aol.com) WILL BE LINK. NEVYAS EYE ASSOCIATES WILL RECEIVE 1 TILE BANNER AD IN PHILADELPHIA, PA ZONE & 1 TILE BANNER AD IN SOUTH NEW JERSEY ZONE. NEVYES EYE WILL RECEIVE MAP LINK, WEB LINK, PHOTO, 25 WORD PRACTICE DESCRIPTION & HIGHLIGHT LISTING ON BASIC LISTINGS IN SAID ZONES.

MOJO INTERACTIVE

7255 ESTAPONA CIRCLE, SUITE 202 FERN PARK, FLORIDA 32730 PH: 407.830.9057 FAX: 407.830.9817

Tile/ Banner Payment Information

Doctor: NEVYAS EYE ASSOCIATES

X Form of Payment (circle one): CHECK VISA MC DISC

X Card Number: _____

X Expiration Date: _____ Amount: $2,500.00

X Signature: _____ Date: _____

Banner Advertisement: 1 TILE BANNER IN PHILADELPHIA, PA. Zone & 1 TILE BANNER AD IN South New Jersey Zone.

Enhanced Listing: BOLD LISTING, WEB LINK, MAP LINK, PHOTO, 25 WORD DESCRIPTION

Total Cost: $2,500.00

Address: 2 BALA PLAZA

City,State, Zip: BALA CYNWYD, PA. 19004

Phone: 610-668-2735

Fax: 610-668-1509

MOJO INTERACTIVE

FAX

To:	DR. RICHARD STERLING	Fax:	610-668-1509
From:	BLAINE A. ROSEBERRY	Date:	4-23-99
Re:	LOCATEADOC.COM	Pages:	04
CC:			

☑ Urgent ☑ For Review ☐ Please Comment ☑ Please Reply ☐ Please Recycl

Comments:

Dear Dr. Sterling: Please find faxed to you the Banner Ad Agreement and Payment Information Page. Please review, complete, sign and fax back to me as soon as possible so that I may lock in these zones for you. As we discussed, if you would like to go to the Allentown zone and or Delaware zone, I will also honor the price of $1150.00 per tile per zone. We are also a leader in the industry in web site design/redesign and recently completed the 200+ page web site for The Lasik Institute. I would be more than happy to work with you on any redesign or hosting options that you might consider down the road for your practice. Please call if you have any questions, toll free 1-877-665-6798 x-102. I look forward to your fax so that we get your banners up and flying.

Sincerely,

Blaine A. Roseberry
Director, Sales & Marketing

MOJO

000040

Locate-A-Doc

4-23-99

Dear HJN:

I wanted to fill you in regarding the web site and working with Locate-A-Doc. I've enclosed the information that we need to secure a site and I told Mr. Roseberry to hold Phila. and S. Jersey for banner ads committing NEA to $2500/yr. He told me to fill out the enclosed forms and give him a credit card number to hold this package. I haven't filled in the credit card number until I received your OK, if you agree it is a good idea please give him your credit card number and fax it to him.

He states that they started in Dec. 1998 and they have 8600 users in 12 different specialties and last month they received 165,000 "hits". In each of their markets they have available 8 banner (also called tiles) ads. In PA they have 6 different regions. I felt that you would definitely want their Phila. region and in NJ their S. Jersey region. The other regions you might be interested in would be central PA and Allentown (Reading, Quakertown etc.) as well as Delaware. To give you an example Barry Concool, MD has contracted with Mojo for Phila., South and North Jersey, Delaware, New York and Fla.?? **Mr. Roseberry said that he would like us to committ today because he's got Schie Eye Institute and Irv Raybar on the edge of signing and taking the rest of the banner ad possiblities**. He's got 3 tile ads in Phila. left and openings in NJ and DE. His fees for these ads per region are $1250/yr/region plus a $100/yr design fee. He will give us the two regions for $2500. I got the feeling if you wanted more regions he would sweeten the deal.

In addition to the above I contacted US Eye Care Providers, LLC group to inquire about their meeting and "concept" (I've enclosed in this fax the invitation letter). I think I told you I spoke with Dr. Sikorski when we were in Puerto Rico. Because of their marketing and claims and infrastructure dev't I think it might be worth the trip to Chicago for the 24 hours. As we progress and get some contracts and the claims come in we might find ourselves in need of such a computer system, as well as their MSO services, that they have committed 6 million dollars to. I called Atlas travel and I could make the trip (I didn't know if you were interested in going) for about $400 ($293 for airfare and $69 for the room).

MOJO INTERACTIVE

FAX

To:	MS. NEVYAS	Fax:	610-668-1509
From:	BLAINE A. ROSEBERRY	Date:	3-19-99
Re:	LOCATEADOC.COM	Pages:	05
CC:			

☑ Urgent ☑ For Review ☐ Please Comment ☐ Please Reply ☐ Please Recycl

Comments:

Dear Dr. Nevyas: Please find faxed to you a summation and proposal based on our conversation this morning. I have also faxed to you the Banner Ad enhancement options for your review as well as our web site packages. As I mentioned, we are also a leader in the industry in web site design/redesign and recently were awarded the 200+ page web site for The Lasik Institute. Please call if you have any questions, toll free at 1-877-665-6798 x-102. I look forward to speaking again soon.

Sincerely,

Blaine A. Roseberry
Director, Sales & Marketing

MOJO INTERACTIVE INC.

877-665-6798 XT 102

000043

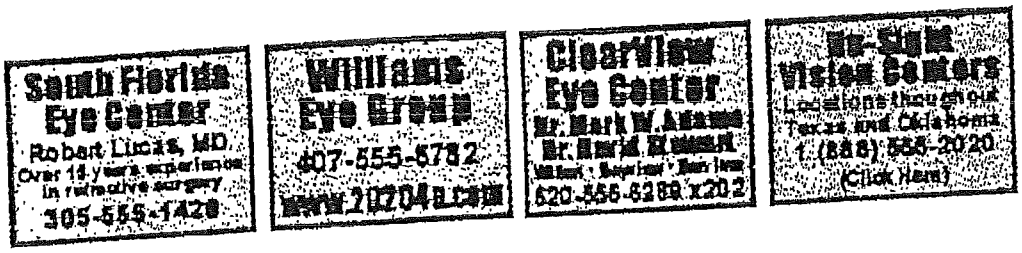
TO:
FROM: Blaine Roseberry, Director of Sales and Marketing
FAX: MOJO INTERACTIVE 1-407-830-9917

FAX

MOJO INTERACTIVE'S

LocateADoc.com

Have a **banner** year and **link** to America's largest **online** patient referral service. Be on top of each page in your specialty, in every city in your state to reach the fastest growing patient base.



Banner ad specials as low as $85 per month

Animation and specialty designs available!

Ask about our cost-effective options below to highlight your **FREE** listing:

- ☐ Add color/boldness to your listing: $10/month
- ☐ 25 word practice description: $30/month
- ☐ Add your practice's logo: $30/month
- ☐ Add your photograph: $30/month

LINKS:

info	map	web site	contact	procedures performed
$25/mo	$35/mo	$50/mo	$10/mo	FREE

Can we create or redesign your existing web site?

Call Toll Free: **1-877-MOJOSYT (1-877-665-6798)** EXT 102 OR 103, EMAIL: sales@locateadoc.com to build your special ad package, to ensure your stay at the top.

000043

MOJO INTERACTIVE

MEMO

March 19, 1999

Nevyas Eye Associates
Attn: Dr. Nevyas
2 Bala Plaza
Bala Cynwyd, Pa. 19004

Dear Dr. Nevyas:

Thank you for speaking with me today regarding how we at MOJO INTERACTIVE will be able to help you promote your practice on the World Wide Web.

At the present time, we have over 113,000 physicians in eleven different specialties on our web site, **LocateADoc.com.** The doctors may be located by patients through state and city searches. We are currently averaging over 4200 prospective patients a day, projecting to some 130,000 potential patients this month. We are excited with this growth and would appreciate the opportunity to have you as the leader in our market in the state of Pennsylvania.

As an incentive for being one of our initial physicians, I would like to make you the following offer. I will upgrade each of your basic listings with your photo, practice description, web site link, map link and highlight your name. This is a value of $155.00 per month per listing that I am offering to you special, for a one payment, one-year agreement of $500.00 per listing. As I mentioned, I do have at this time, 2 tile ads available for the states of NJ, Del., MD. and NY. I can place tile/banner ads, state wide in those states for a one year agreement, one time payment of $1120.00 per tile. This ad will have a direct link to your web site. As we discussed, we are a leader in the industry of web site design/redesign for laser vision surgeons. We can update your web-site as you see fit and have hosting contracts available at discounted rates. If you interested in seeing some of the work we have done on sites, please visit our parent company site, www.mojointeractive.com and you will see under "clients" some of the samples of sites we have done. Let me know about this and I will arrange a conference call to discuss your thoughts.

As I mentioned, if you have the opportunity, please go to our site, **LocateADoc.com** and see for yourself how easy and user friendly that the site is. Also take a look at the video that was produced regarding laser vision surgery. This feature has drawn additional traffic for the Laser Vision Specialists.

Again, I thank you for your time and hope that you will find that we will be a valuable asset to you and your practice. If you have any questions, please feel free to contact me toll free at 1-877-665-6798 x102. I will follow up with you the middle of next week if I don't hear from you before.

Sincerely,

Blaine A. Roseberry
Director, Sales & Marketing

PALM CIRCLE, SUITE 202 | FERN PARK, FLORIDA 32730 | PH: 407.830.9957 | FAX: 407.830.9917

MOJO INTERACTIVE

FAX

To:	Dr. Sterling	Fax:	610.668.1509
From:	Lee Turner	Date:	01.20.00
Re:	Exhibit C	Pages:	2
CC:			

☐ Urgent ☐ For Review ☐ Please Comment ☐ Please Reply ☐ Please Recycle

Comments:

Hi Dr. Sterling. Attached is Exhibit C. If you could just make a not to change the color on the headers, sign it, and then fax it back, we can get rolling. Let me know if there are any questions. Thanks and have a great afternoon! Lee

MOJO

Meeting with Richard Sterling - Notes about the Web Site

General

The navigation bar needs to be much bigger. It is not even apparent that they are navigation items.

The telephone number on there needs to be 1-800-9-LASER6.

You need to look at Dr. Siepser's web site which is www.Siepservision, especially around the way that photographs and graphics are used to highlight and breakup the text, which is much nicer than the straight text that we have.

On every page except the Home Page, the link to the Home Page which is the Nevyas Eye Associates logo needs to have a little word under it that says return to Home or Home or something.

On every page except the Home Page, we need subtitles on the information and we need the List of Links to open up at that subjects link. In other words, you will have the list and the place where you are will have the subtitles of that link also listed as links so that you can go to different places on the page to get the sub-information you need.

There needs to be entire sections added that are going to include Intacs, a section on RC, a section on Refractive Lensectomy, a section on presbyopia treatment.

General Note - All the pages need more photos and graphics. There could be photos of happy patients. Any good photos could be links. You could put a photo of our surgery center and there could be a link to some surgery center information, and things like that.

Your First Step: A Through Evaluation

There needs to be a main item on the navigation bar that says Your First Step or Schedule for Free Evaluation, and it has to be separate from being under from what is now called Procedures and Services.

At the bottom of "Your First Step: A Thorough Evaluation" there has to be another link to the Contact Us page and also the telephone number needs to be changed. Perhaps a link to the web site that explains nearsightedness, farsightedness and astigmatism. I don't think we need to write that again, but we should be able to link to one of them somewhere

When we talk about the first step, we need to tell them all the tests we are going to do, how complete the evaluation is, *(? and that they will be dilated and that they need to leave a certain amount of time for this complete evaluation and that they will need to be out of contact lenses for 72 hours for soft contact lenses and three weeks for rigid contact lenses before proper evaluation can be done?)*

The photos which are of good quality need to be more inviting. They need to invite a person to call, so we need things that look like real people doing things rather than a bunch of professionals. Underneath it should say: Refractive surgery frees you to pursue your lifestyle without glasses or contact lenses.

Going back to the initial navigation bar, there should be perhaps two links. One that says Laser Vision Correction and one that says Other Procedures. That should be on the main listing of Links.

Patient Contact Page

Instead of it saying Patient Contact Page, it needs to say Contact Us. Instead of Procedures and Services, it needs to say more about refractive surgery.

First of all, rename that page Contact Us and then instead of Information Request Form, have it say Tell Us About Yourself.

Again, on that Patient Contact Page, we need to change the telephone number. There should be a thing above the Request Form that says To Help Us Best Answer Your Question, Please Tell Us A Little About Yourself.

On the Information Form, not does the patient wear glasses, contact lenses, it should just say, Do You Wear. It shouldn't say is the patient. It should say Are You.

Again at the bottom of that page, the banner needs a correct phone number.

The Delaware Valley Laser Surgery Institute

The Delaware Valley Laser Surgery Institute page which now says the Laser Surgery Institute, needs to have a picture of the surgery center when you go to it. Also, another photo of patients and nurses inside our lovely surgery center

Physician Bio's

The order up top about doctor biographies needs to be changed. It should be Dr. Anita Nevyas-Wallace then Dr. Herbert Nevyas, then Dr. Joann Yaskin Nevyas, then Dr. Ira B. Wallace, then Dr. Edward Deglin, then Dr. Mitchell Stein, then Dr. Joseph Ortiz, then Dr. Richard Sterling. It needs to be in that particular order.

About Our Practice

About Our Practice page needs to be expanded. We need information on the surgical center. We need information on the other things we do. We need cataract surgery, cosmetic surgery, oculoplastic surgery, glaucoma treatment, retinal surgery, motility and pediatric. All of those things need a paragraph and all of those things should be subtitles that come up on the navigation bar that is on the left side of the page. So immediately when you go to the About Our Practice page the navigation bar should be expanded on the About Our Practice subject heading and it should say Experience You Can Trust, Other Services, Delaware Valley Laser Surgery Institute, Our Surgical Center. All of that needs to be added.

Patient Testimonials

We should immediately transcribe the video tape testimonials that are currently on our video tape and place them on the Web site. The video tape I believe is in Kristin's office or else call ANW with the meeting and she will tell how to get a copy of it and I need you to that this week.

Links

We need a subject heading on the navigation page that simply says Links, to give us all the links as a list.

A note to MOJO, they should contact Intacs to get information that can be placed on the Web site as well as setting up a link to the Intacs Web site. We should have a list of links and it should have a link to the Intacs Web site, a list to the ISRS Web site, the LASIK Institute Web site, and we will grow this list

Procedures and Services

Under Procedures and Services we missed the Laser Eye Surgery Institute. That should actually be in About Our Practice section and it needs to say Delaware Valley Laser Surgery Institute.

There should be a section under Laser Refractive Surgery that talks about surgery for farsightedness and with that should be a short paragraph and a link to the Sunrise site.

The page under Laser Vision Correction that has the Frequently Asked Questions. We need a page that has Questions You Should Ask Any Doctor When Having Laser Vision Correction.

Map and Directions

It is not acceptable to have a map that we go to just the Map Quest site. We either need to enter a map quest query so that they get directly to our site or else we need to copy a map of the area and show ourselves on the map and then after the map give a link to Map Quest for more information. Possibly pictures of each office next to the office address, but certainly a small graphic of the map or we could use the office picture as a link to the map. We need a graphic that shows the map and more and grabs the eye

On the Map and Directions page, there should be a small graphic representing the map along with the link to the map because it is not easy to find the link to the map quickly when you look at that page.

Notes for IBW and RHS

All of the doctor biographies need to be edited to be cleaner and up-to-date. The picture of Dr. Ira Wallace on the Web site needs to be changed. On Dr. Ortiz's page it says to go on to procedures and services. It should say Laser Vision Correction.

Contact Candace and ask her to get some people for testimonials, possibly one of the Parkers who had surgery, possibly any of the ODs who have had surgery, possibly Tammy, Dr. Pasad. Definitely transcribe Glen Macnow from the video. We want to see if we can put a video clip from our MDTV show onto the web site and also we need to have people be able to request a video on the Patient Request Form.

Note to IBW - other web sites to try are Woodums, Mann-Berkley or maybe Berkely-Mann, WendellWong, Ralph Barnett Delaney, Dick Lindstrom's site.

MOJO INTERACTIVE

APPROVAL

Exhibit C
Approval of Design Direction / Site Design

Project Site Address: Neuyas

☑ Okay to proceed as is. / As per our discussions today
☐ Proceed with changes at noted (no new proof necessary)
☐ Make changes as noted (show new proof)

Please change colors of header as discussed

IN WITNESS WHEREOF,

BY: Richard A Ravel .OD

NAME: Richard Stevens, OD

TITLE: Interprofessional Relations

1-20-00
Date

MOJO INTERACTIVE

MOJO INTERACTIVE

ACCOUNT INFO

DATE: 7-27-99
8-10-99

Client Contract: Nevyas Project Site

Fax Number: (610)668-1509

Registered Domain Name: www.nevyas.com

Project Site Address: www.mojointeractive.com/nevyas.com/projectsite/

Username: nevyas

Password: Surgery

NOTES: Please contact me if you have any questions.
We have begun design.
Thanks - Christina :)

If you have questions or problems with your account or the project site please contact Christina Brooks at 1.877.665.6798 x107 or christina@mojointeractive.com

Jul-29-99 03:22P

MOJO INTERACTIVE

ACCOUNT INFO

DATE: 7-29-99

Client Contract: Nevyas Eye Associates

Fax Number: (610) 668-1509

Registered Domain Name: Nevyas.com

Project Site Address: www.mojointeractive.com/nevyas.com/projectsite

Username: nevyas Nevyas

Password: surgery

NOTES: Please call me with any questions.
Christina

If you have questions or problems with your account or the project site please contact Christina Brooks at 1.877.665.6798 x107 or christina@mojointeractive.com

000052

Also,

Please send us 5 to 10 Search words that you would like to be linked to. These words you can tell friends, family, and colleagues and they will be able to find your site without knowing or remembering the address.

1)
2)
3)
4)
5)
6)
7)
8)
9)
10)

Doctor: Dr. Nevyas Practice: _____

Materials Checklist

This checklist is designed to help you put together all of the material we will need to design and create your web site. The following is a list of items that should be included in the materials you are sending us:

- ☐ Camera ready copy of your logo
- ☐ Photographs of doctors, office, staff, testimonial clients, etc. *(Originals will be returned to you. Please write the doctor's name on the back of each picture.)*
- ☐ General information and history about your practice.
- ☐ Doctor Biographies and/or Curriculum Vitae.
- ☐ Information about the procedures and services your practice performs *(video of procedures can be added for an additional fee).*
- ☐ Camera ready map to your office(s).
- ☐ Written directions on how to find your office from popular locations.
- ☐ All existing marketing materials expressing your practice's look and feel.
- ☐ Patient testimonials.
- ☐ Outcomes statistics and graphs.
- ☐ Questions and answers to commonly asked questions by patients.
- ☐ Patient education materials and graphics. Please do not send any copyrighted material.
- ☐ Completed contracts and paperwork.
- ☐ Email address for web site links and online contact form.

(NOTE: Please send us all of the above information via mail. Text materials can be sent in disk format or by electronic mail.)

MOJO
7233 ESTAPONA CIRCLE, SUITE 202 | PERK PARK, FLORIDA 32730 | PH: 407.830.9937 | FAX: 407.830.9917
www.mojointeractive.com | www.locatedoc.com

Doctor: DR. NEVYAS Practice: _____

Project Profiler

The Project Profiler will give Mojo Interactive a general idea of the look, feel, and layout you would like to have on your web site. This will aid us in the design of the site. Please check all the boxes that apply.

Site Feel

- ☐ I would like a mainly informative site.
- ☐ I would like a site that reinforces my practice's marketing/branding image.
- ☐ I would like a site that is a balance of the above two options.

Site Look

- ☐ I have a specific or general idea of how I'd like the site to look. Please see my description below: _____
- ☐ I would like the site to look similar to my company's marketing materials (I have sent or will send you a copy of my company's marketing materials as a guide).
- ☐ I am leaving it up to Mojo Interactive to develop the look of the site
- ☐ I would like my company colors to be the main colors on the site. These color(s) are: _____

Site Sections

Choose the 4 to 6 sections you would prefer be used to organize your web site:

- ☐ Welcome
- ☐ About Our Practice
- ☐ Doctor Biographies
- ☐ Procedures/Services
- ☐ General Information
- ☐ Testimonials
- ☐ Map/Directions
- ☐ Patient Contact Page
- ☐ Outcomes
- ☐ Other Section(s) _____

Doctor: Dr. Nevyns Practice: _____

Materials Checklist

This checklist is designed to help you put together all of the material we will need to design and create your web site. The following is a list of items that should be included in the materials you are sending us:

- ☐ Camera ready copy of your logo
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- ☐ Information about the procedures and services your practice performs *(video of procedures can be added for an additional fee).*
- ☐ Camera ready map to your office(s).
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- ☐ All existing marketing materials expressing your practice's look and feel.
- ☐ Patient testimonials.
- ☐ Outcomes statistics and graphs.
- ☐ Questions and answers to commonly asked questions by patients.
- ☐ Patient education materials and graphics. Please do not send any copyrighted material.
- ☐ Completed contracts and paperwork.
- ☐ Email address for web site links and online contact form.

(NOTE: Please send us all of the above information via mail. Text materials can be sent in disk format or by electronic mail.)

MOJO

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www.mojointeractive.com | www.locateadoc.com

6/6/00

IBW:

I spoke with Lee Turner from Mojo today and he said that the only expense we'll run into is color or design change not necessarily the following changes we determined in the meeting we had a few weeks ago. I thought I'd list for you the changes I've marked down and I'll fax those to Turner so he might value the charges. Please edit and give me your additons so that I might get them working on this ASAP.

- Change pictures on home page
- Change phone number to 1-800-9LASER-6
- One of the tag lines should read "Refractive Surgery liberates you from you CL's and or glasses
- Links should be bigger
- Must have a direct e-mail link back to NEA on every page "Contact us" instead of Contact
- Put Home link label on each page
- More about refractive surgery under procedures and services
- More graphics
- More pictures
- Add videos of surgery??
- Links to testimonials (while we're at it we need to transcribe testimonials from MDTV video
- Include a call for video tape

I'm sure there's more but this is what I had written down. I'll start this process whenever I get your feedback.

Rich

AGREEMENT

MOJO INTERACTIVE

HOST SERVICE AGREEMENT

This Agreement is made between Nevvas Eve Associates ("Client"), having its principal place of business at 2 Bala Plaza, Bala Cynwyd, Pa. 19004, and Mojo Interactive Corporation ("MOJO"), having its principal place of business at 7255 Estapona Circle, Suite 202, Fern Park, Florida 32730

WHEREAS Client desires MOJO to serve as the Host Facility for Client's WebSite for public access to the WebSite and to provide support for client's WebSite on an as needed basis.

NOW, THEREFORE, in consideration of the mutual covenants and promises set forth herein, the parties agree as follows:

A. PREAMBLE

The primary purpose of MOJO is to provide facilities and support for the maintenance of WebSites which can be accessed through the numerous computer networks commonly referred to collectively as "The Internet." It is Client's intention to allow MOJO users to maintain control over the contents of their WebSites with minimal or no interference from MOJO.

MOJO has developed Acceptable Use Policies (AUP) contained herein. The AUP is intended to inform MOJO's clients of what MOJO considers to be acceptable conduct in relation to use of MOJO's server facilities and to inform clients what actions MOJO may take, with or without notice, in the event that MOJO becomes aware of inappropriate use of MOJO's service. This AUP will be used to help MOJO system administrators deal with complaints, and to determine when action should be taken. It is expected that all MOJO Clients will follow the policies set forth herein. These policies are drawn from applicable law and generally accepted standards of Internet conduct, and are intended to ensure protection of MOJO's technical resources, ability to continue to provide high quality service to its clients, and the protection of MOJO's reputation as a Host Facility.

B. MOJO'S HOST SERVICE, INCLUDING E-MAIL ACCESS IS PROVIDED SUBJECT TO THE FOLLOWING TERMS AND CONDITIONS

1. Definitions

As used in this Agreement, the following terms shall apply:

(a) "Domain Name" shall mean the address of a WebSite.

(b) "E-Mail" shall mean the transmission of memos and messages over a network, including but not limited to the Internet.

(c) "Host Facility" shall mean MOJO's own computer server or any computer server on which MOJO has the right to store information which can be accessed through the Internet.

(d) "HyperText Markup Language" (HTML) shall mean the standard for encoding documents for use and display on networks and the Internet.

(e) "Hypertext or Hyperlink" shall mean a predefined linkage between one file and another file, either within a WebSite or between WebSites.

(f) "Internet" shall mean the large world-wide network made up of a number of smaller interconnected networks.

(g) "IRC bot" is a program which runs and is connected to an IRC server 24 hours a day, automatically performing certain actions.

(h) "Maintenance Support" shall mean only minor changes in the text of the Client's WebSite, modification of E-mail forwarding services, elimination or particular pages or

passages, and necessary repairs should the WebSite malfunction. Support does not include the creation of additional pages or other complex changes.

(i) "Page" shall mean one 81/2 x 11 piece of paper or the amount of information contained therein using a font size of 12 point or larger.

(j) "WebSite" shall mean a series of files, sharing a common subject matter that cumulatively comprises HTML images, text, and other forms of information suitable for viewing with one of the standard web browsers.

(k) "World Wide Web" shall mean the entire collection of WebSites available for public access on the Internet.

2. Compensation

MOJO will serve as the Host Facility for Client's WebSite to Client for a period of 15 (_) months, for a fee of $ 0.00. Payment for hosting required before any services will be started. Should Client intend to renew the monthly charge will be $45.00.

3. Duties

MOJO agrees to provide maintenance support for Client's WebSite for the term of this agreement.

4. Warranties/Disclaimers

Sevices provided by Mojo on an "as is" basis. No warranties, express or implied, are made with respect to MOJO Host Service. You release MOJO from and MOJO shall have no liability or responsibility for any direct, indirect, incidental or consequential damages suffered by you in connection with your use of or inability to use or access the MOJO services including, but not limited to, damages from loss of data resulting from delays, non-deliveries, mis-deliveries, or service interruptions, or due to inadvertent release or disclosure of information even if the same is caused by MOJO's own negligence. Without limiting the generality of the foregoing, MOJO disclaims to the full extent permitted by applicable law any responsibility for (and under no circumstances shall be liable for) any conduct, content, goods and services available on or through the Internet or MOJO.

4.1 UNDER NO CIRCUMSTANCES SHALL MOJO BE LIABLE FOR ANY INCIDENTAL, INCONSEQUENTIAL, SPECIAL OR INDIRECT DAMAGES ARISING OUT OF OR RELATED TO THIS AGREEMENT, EVEN IF MOJO WAS INFORMED OF OR OTHERWISE AWARE OF THE POSSIBILITY THEREOF.

4.2 MOJO warrants that the services it performs in maintaining its Host Facility and Client's WebSite will be rendered in a competent, professional manner. MOJO does not warrant and specifically disclaims any representations that its Host Facility will meet Client's requirements or that its maintenance of client's WebSites will be error-free. EXCEPT AS EXPRESSLY SET FORTH IN THIS PARAGRAPH, MOJO DISCLAIMS ALL OTHER EXPRESSED WARRANTIES AND ALL WARRANTIES, DUTIES AND OBLIGATIONS IMPLIED IN LAW. MOJO's limited warranty set forth herein is in lieu of all liabilities or obligations of MOJO for damages arising out of or in connection with its Host Facility.

4.3 MOJO is not obligated to verify the accuracy of any information contained on a Client's WebSite or verify that the information is any other way proper and acceptable, provided however, that MOJO reserves the right to:

(a) Modify or delete any information or graphics supplied by Client in order to comply with current and future technical limitations and business requirements of MOJO.

(b) Modify, delete or suspend dissemination or display of any information or graphics supplied by Client if MOJO receives any complaints about Client's information or advertising:

(1) being false, deceptive, unfair or inaccurate;

(2) violating another's intellectual property right; or

(3) containing language which defames or libels another or another's works.

(c) Modify, delete or suspend dissemination or display of any information or graphics supplied by Client if MOJO has reason to believe such information violates any local, state or federal laws.

(d) Suspend dissemination and display of the Client's Internet WebSite, if Client has not made a payment as required by this Agreement, or if MOJO determines that the information on the Client's Internet page will damage the reputation of MOJO.

5. Security

The Client is responsible for all use of the Client's e-mail account(s) and confidentiality of password(s), including choosing safe passwords and ensuring file protections are set correctly. MOJO will suspend access or change access to Client's e-mail account(s) immediately upon notification by Client that Client's password has been lost, stolen or otherwise compromised. MOJO is not liable for any usage and/or charges prior to MOJO making the necessary account alteration.

6. Personal Files

MOJO is not responsible for any Client's personal files residing on MOJO's Host Facility. The Client is responsible for independent backup of the Client's data that is stored on MOJO's Host Facility. MOJO reserves the right to delete any Client's personal files after one or both parties terminate the service agreement between MOJO and the Client.

7. Non-Transferability of Account

The right to services provided by Mojo hereundo is not transferable. Use of MOJO E-Mail accounts is expressly limited to the individual or business whose name appears on the account.

8. Network Address Ownership

Any network address assignments issued by MOJO are the property of MOJO and are considered to be on loan to its clients. In the event service with MOJO is discontinued for any reason, such addresses will revert to MOJO. If a Client of MOJO participates in a service of MOJO which provides for a unique Domain Name System (DNS) entry, the Client will retain ownership of the assigned Domain Name, but not the IP address to which it was assigned by MOJO.

9. Acceptable Use Policies

9.1 Compliance with all Laws

Client agrees to use the service in a manner consistent with any and all applicable laws and regulations of the United States of America, the State of Florida, and the Client's locality. Reproduction or transmission of any material in violation of any local, state, U.S., or international law or regulation is prohibited. The Client agrees that any material to be reproduced or transmitted on MOJO's Host Facility through Client's e-mail account(s) or WebSite does not violate or infringe any copyright, trademark, patent, statutory common law or proprietary rights of others, or contain obscene, libelous or threatening material. The Client shall defend, indemnify and hold harmless MOJO from and against any claims, liabilities and expenses, including attorney fees, resulting from any Client's use of the MOJO service or a Client's account in an unlawful manner or otherwise in violation of or contrary to the Client's Agreement with MOJO or MOJO's Acceptable Use Policies. At MOJO's discretion, MOJO may revoke a Client's access to MOJO services or e-mail accounts for inappropriate usage.

(a) Client represents and warrants to MOJO that client owns or otherwise has the right to display and disseminate the information and content provided on the Client's Internet page, and that such information and content does not infringe on the intellectual property rights of any third party. Client represents and warrants that it has obtained, and currently has, any and all grants of rights from third parties which may be required to display text, graphics or other materials in the information contained on Client's Internet page.

9.2 Unacceptable Conduct

The following types of conduct are grounds for immediate suspension of service pending investigation by MOJO and may result in termination of this agreement by Mojo.

(a) Sending unsolicited mass Electronic Mailings from the MOJO Host Facility (i.e., to more than 25 users) which provoke complaints from the recipients.

(b) Engaging in unsolicited mass Electronic Mailings from a provider other than MOJO and using an account on MOJO as a mail drop for responses, or to draw attention to a Web Site housed within MOJO's facility.

(c) Continued harassment of other individuals on the Internet after being asked to stop by those individuals and/or by MOJO.

(d) Sending large volumes of unsolicited E-Mail to individuals or to individual business accounts.

(e) Impersonating another user or otherwise falsifying one's user name in E-Mail. (This does not preclude the use of nicknames in IRC or the use of anonymous remailer services.)

(f) Attempts, whether successful or not, to gain access to any other system or users' private data without express consent of the user.

(g) Use of IRC bots or clonebots on MOJO, whether on IRC servers controlled by MOJO or by other parties.

(h) Attempts to interfere with the regular workings of MOJO's systems or network connections or which adversely affect the ability of other people or systems to use MOJO services or the Internet, including, but not limited to:

(1) any unauthorized attempts by a user to gain root access or access to any account not belonging to that user on this or any other MOJO system;

(2) any use of this or any other MOJO system as a staging ground to disable other systems.

(i) Any activity which violates any local, state or federal laws or statutes.

9.3 Excess Utilization of System or Network Resources

MOJO account descriptions in some cases may specify limits on bandwidth, CPU and disk utilization for certain types of Clients, and use up to these limits is included in the price for that type of Client. In the event MOJO determines that a Client is exceeding the bandwidth, CPU and/or disk utilization limits, the Client will be notified by E-Mail. If excessive bandwidth, CPU or disk space utilization is determined by MOJO to adversely affect MOJO's ability to provide service for all clients, immediate action may be taken to alleviate the problem. In such event, the Client will be notified by E-Mail as soon as practicable.

9.4 Compliance with Rules of Other Networks

Any access to other networks connected to MOJO's Host Facility must comply with the rules for that other network as well as with MOJO's rules.

9.5 Monitoring/Privacy

MOJO reserves the right to monitor any and all communications through or with MOJO facilities. Client agrees that MOJO is not considered a secure communications medium for the purposes of the Electronic Communications Privacy Act, and that no expectation of privacy is afforded. It may become necessary for MOJO employees to examine system accounting logs and other records to determine if privacy violations or other network unfriendly activities have occurred. MOJO also reserves the right to access a Client's mailbox or other files stored on MOJO systems to resolve system problems or mail system errors.

9.6 Cooperation with Authorities

MOJO reserves the right to cooperate fully with law enforcement and other authorities in investigating claims of illegal activity including, but not limited to, illegal transfer or availability of copyrighted material, postings or e-mail containing threats of violence or other illegal activity.

9.7 Confidentiality of Personal Subscriber Information

MOJO will not release a client's subscriber information, nor a Client's billing information, to any third party except upon presentation of a valid court order of a government or entity within our jurisdiction. Client agrees that MOJO's judgment as to the validity of any court order of subpoena shall be considered proper and final.

9.8 MOJO's Right to Suspend or Cancel Account

MOJO reserves the right to suspend or cancel service to a Client at any time and without notice, for any reason, including, but not limited to, refusal or failure to pay for services provided by sole judgment of MOJO that the Client may be performing activities harmful to MOJO or its Clients, employees, vendors, business relationships or any other users of the Internet.

9.9 Right to Damages

MOJO reserves the right to collect damages (software, hardware and man hours) if any harm is done to MOJO by Client which requires repair or reconfiguration of any kind.

9.10 Other Remedies/Non-Waiver

Nothing contained in these policies shall be construed to limit action MOJO may take or remedies available to MOJO in any way with respect to any of the described conduct. MOJO reserves the right to take any additional actions MOJO may consider appropriate with respect to such conduct, including without limitation taking action to recover the costs and expenses of identifying offenders and removing them from the MOJO Host Facility. In addition, MOJO reserves at all times all rights and remedies available to MOJO with respect to such conduct at law or in equity. Non-enforcement of any policy or rule herein does not constitute consent or waiver, and MOJO reserves the right to enforce such policy or rule at its sole discretion.

9.11 MOJO's Right to Change Service

MOJO reserves the right to change without notice the MOJO service, including, but not limited to, access procedures, hours of operation, menu structures, commands, documentation, vendors and services offered.

9.12 MOJO's Right to Modify its Acceptable Use Policies

MOJO may modify its Acceptable Use Policies upon notice via E-mail to Client. Client's use of MOJO services after such notice shall constitute Client's acceptance of the modifications to these policies.

9.13 Indemnifications

Client agrees to defend, indemnify and hold harmless MOJO and its owners, officers, shareholders, directors, employees, affiliates and subsidiaries from and against any and all claims, demands, liabilities, proceedings, damages, injuries, losses, costs and expenses (including, without limitation, reasonable attorneys' fees) arising out of or related to:

(a) Any acts or omissions by Client undertaken in connection with the Client's Web Site page. including, without limitation, those arising out of or related to any branch of:

(1) any Client warranties, representations, or covenants hereunder;

(2) inaccuracy of any information, including false advertising claims and unfair competition claims;

(3) Claims and investigations made by any local, state or federal agency arising out of information contained on the Client's Internet page.

(b) Violations of any third-party intellectual property rights, or any claim of infringement, misappropriation or violation of a right of a third party (including, without limitation, a trade secret claim, defamation or libel claim, or an obscenity claim).

10. Miscellaneous Provisions

10.1 Prevention of Performance.

The parties shall not be liable for any delay or failure of performance of this Agreement if such failure is caused by acts of God, war, Governmental decree, power failure, judgment or order, strike, communications failure, equipment or software malfunction, or other circumstances, whether or not similar to the foregoing, which are beyond the reasonable control of such party.

10.2 Entire Agreement.

This instrument embodies the whole agreement between the contracting parties. The agreement supersedes and nullifies all prior understandings, promises, and undertakings, if any, made orally or in writing by or on behalf of the parties with respect to the subject matter hereof, and may not be modified, altered or terminated except in a writing signed and dated by the parties.

10.3 Severability.

The provisions of this Agreement are severable. If any provision is determined by a court of competent jurisdiction or a governmental regulatory entity to be invalid or unenforceable, in whole or in part, that provision shall be construed or limited in such a way as to make it enforceable, consistent with the manifest intentions of the parties. If such a construction or limitation is not possible, the unenforceable provision will be stricken, and the remaining provisions of this Agreement will remain valid and enforceable.

10.4 Joint Venture.

Nothing contained herein shall be construed to place the parities in the relationship of partners or joint venturers nor constitute any party the agent of any other party, and neither party shall have the power to obligate or bind the other party in any manner whatsoever.

10.5 Waiver.

Failure by either party to insist upon the strictest performance or observance of any provision of this Agreement or to exercise any right or remedy arising out of this Agreement shall not be construed as a waiver of any right or remedy with respect to any existing or subsequent breach or default.

10.6 Notices.

Any and all written notices, communications, or payments shall be made to the respective parties at their addresses indicated in the first paragraph of this Agreement or at such other address as a party may indicate in a written notice to the other party to this Agreement.

10.7 Governing Law.

This Agreement shall be governed by the internal laws of the State of Florida and the parties hereto agree that the courts in the State of Florida shall have exclusive jurisdiction for any claims or disputes which may arise hereunder.

11. Litigation

In the event that enforcement of this Agreement becomes necessary(whether suit be brought or not), the prevailing party shall be entitled to recover, in addition to all other remedies available at law, an amount equal to all costs and expenses incurred in connection with such enforcement, including reasonable attorney's fees at the trial level and in connection with all appellate proceedings.

In the event of any legal or equitable action arising under this Agreement, the parties agree that jurisdiction and venue of such action shall lie exclusively within the state courts of Florida located in Orange County, Florida, or the United States District Court for the Middle District of Florida, Orlando Division, and the parties specifically waive any other jurisdiction and venue.

12. Assignment

Client may not assign this Agreement without the consent of Mojo.

13. Government Requirements

Each party hereto shall comply with all statutes, ordinances and government regulations in the conduct of its business.

IN WITNESS WHEREOF, Client and MOJO have duly executed this Contract as of the day and year executed below.

MOJO Interactive

By: _____

Name: _____
Title: _____
Date: _____

Nevvas Eve Associates

By: _____

Name: Herbert S Nevvas
Title: _____
Date: 6/16/04

Any and all written notices, communications, or payments shall be made to the respective parties at their addresses indicated in the first paragraph of this Agreement or at such other address as a party may indicate in a written notice to the other party to this Agreement.

20. Governing Law.

This Agreement shall be governed by the internal laws of the State of Florida and the parties hereto agree that the courts in the State of Florida shall have exclusive jurisdiction for any claims or disputes which may arise hereunder.

21. Litigation.

In the event that enforcement of this Agreement becomes necessary (whether suit be brought or not), the prevailing party shall be entitled to recover, in addition to all other remedies available at law, an amount equal to all costs and expenses incurred in connection with such enforcement, including reasonable attorney's fees at the trial level and in connection with all appellate proceedings.

In the event of any legal or equitable action arising under this Agreement, the parties agree that jurisdiction and venue of such action shall lie exclusively within the state courts of Florida located in Orange County, Florida, or the United States District Court for the Middle District of Florida, Orlando Division, and the parties specifically waive any other jurisdiction and venue.

22. Assignment

Client may not assign this Agreement without the consent of Mojo.

23. Government Requirements

Each party hereto shall comply with all statues, ordinances and government regulations in the conduct of its business.

IN WITNESS WHEREOF, Client and Mojo have duly executed this Contract as of the day and year executed below.

Mojo Interactive

By: _____

Name: _____

Title: _____

Date: _____

Client: NEVADA EYE ASSOCIATES

By: _____

Name: Herbert T. Meyer

Title: President

Date: 6/10/99

MAY 10 1999

MOJO INTERACTIVE

MEMO

May 6, 1999

Nevyas Eye Associates
Attn: Dr Richard Sterling
2 Bala Cynwyd Plaza
Bala Cynwyd, Pa. 19004

Dear Dr. Sterling:

Thank you for allowing us at Mojo Interactive the privilege to work with you in the redesign of your website. I know that it will be a positive experience for both as we reintroduce Nevyas Eye Associates to the World Wide Web.

You will find the Web Creation Agreement, Host Service Agreement, Website Payment page, materials checklist and project profiler. Please review, complete, sign and return the signed agreements along with the deposit as soon as possible so that we can guarantee these prices for you. We anticipate price increases toward the end of the month and I shall honor this quote to you. As we discussed, we can add additional content above the allocated package pages at $60.00 per page. We will also be able to add videos and listing of providers as we go. Please refer to my letter dated May 5, 1999 reflecting those prices. I do not anticipate increases in these prices through the end of this year.

Again, thanks for choosing Mojo Interactive to work with you on this special project. Please call if you have any questions, toll free at 1-877-665-6798 x-102.

Sincerely,

Blaine A. Roseberry
Director, Sales & Marketing

MOJO

060005

MOJO INTERACTIVE

FAX

To:	DR. RICHARD STERLING	Fax:	610-668-1509
From:	BLAINE A. ROSEBERRY	Date:	5-5-99
Re:	WEB SITE REDESIGN	Pages:	02
CC:			

☐ Urgent ☑ For Review ☐ Please Comment ☑ Please Reply ☐ Please Recycle

Comments:

Dear Dr. Sterling: Please find faxed to you the proposal that we discussed yesterday regarding the redesign of the www.nevyas.com web site. I covered all of the points you outlined and broke out the prices according to options included with the "Advanced Cyber Package". Please call with any questions. I look forward to starting this important project for you. My toll free number is 1-877-665-6798 x-102. I will await your call.

Sincerely,

Blaine A. Roseberry
Director, Sales & Marketing

MOJO

MOJO INTERACTIVE

7255 ESTAPONA CIRCLE, SUITE 202 FERN PARK, FLORIDA 32730 PH: 407.830.0957 FAX: 407.830.9917

Deposit

Web Site Design Payment Information

Doctor: NEVYAS EYE ASSOCIATES

X Form of Payment (circle one): CHECK VISA MC DISC

X Card Number: _____

X Expiration Date: _____

TOTAL Amount: $2,995.00 DEPOSIT: $1,497.50

X Signature: _____

Date: _____

Address: 2 BALA CYNWYD

City, State, Zip: BALA CYNWYD, PA. 19004

Phone: 610-668-2777

Fax: 610-668-1509

Doctor: NEVYAS Practice: NEVYAS EYE ASSOCIATES

Materials Checklist

This checklist is designed to help you put together all of the material we will need to design and create your web site. The following is a list of items that should be included in the materials you are sending us:

- ☐ Camera ready copy of your logo.
- ☐ Photographs of doctors, office, staff, testimonial clients, etc. *(Originals will be returned to you. Please write the doctor's name on the back of each picture.)*
- ☐ General information and history about your practice.
- ☐ Doctor Biographies and/or Curriculum Vitae.
- ☐ Information about the procedures and services your practice performs *(video of procedures can be added for an additional fee).*
- ☐ Camera ready map to your office(s).
- ☐ Written directions on how to find your office from popular locations.
- ☐ All existing marketing materials expressing your practice's look and feel.
- ☐ Patient testimonials.
- ☐ Outcomes statistics and graphs.
- ☐ Questions and answers to commonly asked questions by patients.
- ☐ Patient education materials and graphics. Please do not send any copyrighted material.
- ☐ Completed contracts and paperwork.
- ☐ Email address for web site links and online contact form.

(NOTE: Please send us all of the above information via mail. Text materials can be sent in disk format or by electronic mail.)

MOJO

7255 ESTAPONA CIRCLE, SUITE 202 | FERN PARK, FLORIDA 32730 | PH: 407.830.9957 | FAX: 407.830.9917

www.mojointeractive.com | www.locateadoc.com

Doctor: NEVYAS Practice: NEVYAS EYE ASSOCIATES

Project Profiler

The Project Profiler will give Mojo Interactive a general idea of the look, feel, and layout you would like to have on your web site. This will aid us in the design of the site. Please check all the boxes that apply.

Site Feel

- ☐ I would like a mainly informative site.
- ☐ I would like a site that reinforces my practice's marketing/branding image.
- ☐ I would like a site that is a balance of the above two options.

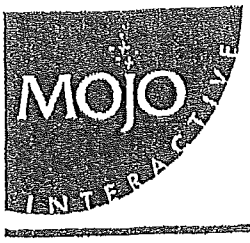
Site Look

- ☐ I have a specific or general idea of how I'd like the site to look. Please see my description below: _____
- ☐ I would like the site to look similar to my company's marketing materials (I have sent or will send you a copy of my company's marketing materials as a guide).
- ☐ I am leaving it up to Mojo Interactive to develop the look of the site.
- ☐ I would like my company colors to be the main colors on the site. These color(s) are: _____

Site Sections

Choose the 4 to 6 sections you would prefer be used to organize your web site:

- ☐ Welcome
- ☐ About Our Practice
- ☐ Doctor Biographies
- ☐ Procedures/Services
- ☐ General Information
- ☐ Testimonials
- ☐ Map/Directions
- ☐ Patient Contact Page
- ☐ Outcomes
- ☐ Other Section(s) _____



AGREEMENT

MOJO INTERACTIVE

WEBSITE CREATION AGREEMENT

This Agreement is made between Nevvas Eye Associates ("Client"), having its principal place of business at 2 Bala Cynwyd Plaza Bala Cynwyd, Pa. 19004, and Mojo Interactive Corporation ("Mojo"), having its principal place of business at 7255 Estapona Cirlce, Suite 202, Fern Park, Florida 32730.

WHEREAS Client desires Mojo to create and develop a WebSite suitable for access on the Internet.

NOW, THEREFORE, in consideration of the mutual covenants and promises set forth herein, the parties agree as follows:

1. **Definitions**

As used in this Agreement, the following terms shall apply:

(a) "Confidential Information" shall mean any information relating to or disclosed in the course of the Agreement, which is marked as "confidential" or "proprietary" by the disclosing party. Confidential information shall not include any information which is or becomes generally available to the public without breach of this Agreement; is in the possession of a party prior to its disclosure by the other party; or becomes available from a third party not in breach of any obligations of confidentiality to the disclosing party.

(b) "Domain Name" shall mean the address of a WebSite.

(c) "E-Mail" shall mean the transmission of memos and messages over a network, including but not limited to the Internet.

(d) "Host Facility" shall mean Mojo's own computer server or any computer server on which Mojo has the right to store information which can be accessed through the Internet.

(e) "HyperText Markup Language" (HTML) shall mean the standard for encoding documents for use and display on networks and the Internet.

(f) "Hypertext or Hyperlink" shall mean a predefined linkage between one file and another file, either within a WebSite or between WebSites.

(g) "Internet" shall mean the large world-wide network made up of a number of smaller interconnected networks.

(h) "Page" shall mean one 8 1/2 x 11 piece of paper or the amount of information contained therein using a font size of 12 point or larger

(i) "WebSite" shall mean a series of files, sharing a common subject matter that cumulatively comprises HTML images, text, and other forms of information suitable for viewing with one of the standard web browsers.

(j) "World Wide Web" shall mean the entire collection of WebSites available for public access on the Internet.

2. **Compensation and Terms**

Mojo shall perform the work shown in Exhibit A, according to the timetable shown in Exhibit B.

The fee for the work shown in Exhibit A is $2,995.00. Fifty percent (50%) of the fee ($1,497.50) is due upon signing the contract. Twenty-five percent (25%) of the fee ($748.75) is due upon signing Exhibit C. The remainder ($748.75) is due within 30 days of completion of the work shown in Exhibit A.

In the event that travel to Client's place of business is necessary, Client shall reimburse Mojo for reasonable business and travel expenses upon submission of expense reports with back-up documentation.

If Mojo brings a legal action to collect any sums due under this Contract, it shall be entitled to collect, in addition to all damages, its costs of collection, including reasonable attorneys' fees.

This Contract shall remain in effect until all obligations under this Contract have been completed, and the Final Acceptance Certificate (Exhibit D) has been signed by Client.

3. Warranties

Each party represents and warrants to the other that it has the power and authority to enter into and perform this ContractT.

4. Independent Contractor

Mojo acknowledges that the services rendered under this Contract shall be solely as an independent contractor. Mojo shall not enter into any contract or commitment on behalf of Client without Client's written consent. Mojo further acknowledges that it is not considered an affiliate or subsidiary of Client, and is not entitled to any Client employment rights or benefits. It is expressly understood that this undertaking is not a joint venture.

5. Grant

Mojo shall own the copyright of the WebSite. Mojo grants the Client license to use the WebSite, to reproduce it for Client's own use, and to prepare derivative works for its own use, regardless of whether the WebSite is maintained by Mojo or by another party. Client shall own the copyright of all materials, including graphics, prospectuses and advertising copy, that it provides to Mojo for inclusion in the WebSite.

6. Original Material

Client shall supply to Mojo material for inclusion in its WebSite, including prospectuses, graphics and advertising copy. All photographs, trademarks, images or other works owned or controlled by Client and which are specified by Client for inclusion in the WebSite shall be provided by Client in clear and camera-ready form necessary for digital translation or in other format agreed upon by the parties.

7. Compliance

Client assumes all responsibility for complying with local, state and federal securities regulations and laws. Mojo shall not make public any portion of the WebSite without first obtaining Client's express written approval. Client shall convey its written approval with the form in Exhibit C.

8. Acknowledgment

Mojo may include at the bottom of Client's WebSite a notice that it is the creator and maintainer of the WebSite, a copyright notice, and a hypertext link to the WebSite of Mojo.

9. Termination and Cancellation

(a) This Agreement may be terminated upon the occurrence of one or more of the following events, and the terminating party shall not be liable to the other party solely for the rightful exercise of such right:

(1) By either party if the other party seeks protection under the bankruptcy laws (other than as a creditor) or any assignment is made for the benefit of creditors or if a trustee is appointed for all or any portion of such party's assets; or

(2) By either party if the other party is in default of any material provision of this Agreement and such default is not cured within 15 days after receipt of written notice (as provided in Paragraph 19) thereof by such other party.

(b) This Agreement may be terminated by Client for Client's convenience upon 15 days' prior written notice to Mojo (as provided in Paragraph 19); provided, however, that Client pay to Mojo, pro rata, for work completed. Thereafter,

Client shall obtain all rights to the partially completed WebSite as provided in Paragraph 5.

10. Indemnity

Client shall indemnify Mojo against and hold Mojo harmless from any and all claims, actions, suits, proceedings, costs, expenses, damages and liabilities, including attorneys' fees, claimed by any person, organization, association, or otherwise arising out of, or relating to, the WebSite or its creation, use, possession, operation and/or condition.

11. Taxes

Client shall be responsible for the payment of all local, excise, sales, use, property and other taxes or charges levied with respect to this contract.

12. Enhancements

Client may exercise the option, at any time, to add to this Contract any of the other services offered by Mojo at the then market price for those services.

13. Confidential Information

Each party acknowledges that it may receive Confidential Information of the other party relating to its technical, marketing, product and/or business affairs. All confidential information of the other party shall be held in strict confidence and shall not be disclosed or used without the express written consent of the other party, except as may be required by law. Each party shall use reasonable measures and reasonable efforts to provide protection for Confidential Information.

Each party hereby acknowledges that unauthorized disclosure of confidential information could cause irreparable harm and significant injury to the disclosing party that make be difficult to ascertain. Accordingly, each party agrees that the disclosing party will have the right to seek and obtain immediate injunctive relief to enforce obligations under this Agreement, in addition to any other rights and remedies each party may have.

14. Assignment

The services to be rendered hereunder shall be performed by Mojo, but such services may be subcontracted or otherwise performed by third parties on behalf of Mojo without prior written permission of Client.

15. Prevention of Performance.

The parties shall not be liable for any delay or failure of performance of this Agreement if such failure is caused by acts of God, war, Governmental decree, power failure, judgment or order, strike, communications failure, equipment or software malfunction, or other circumstances, whether or not similar to the foregoing, which are beyond the reasonable control of such party.

16. Entire Agreement.

This instrument embodies the whole agreement between the contracting parties. The agreement supersedes and nullifies all prior understandings, promises, and undertakings, if any, made orally or in writing by or on behalf of the parties with respect to the subject matter hereof, and may not be modified, altered or terminated except in a writing signed and dated by the parties.

17. Severability.

The provisions of this Agreement are severable. If any provision is determined by a court of competent jurisdiction or a governmental regulatory entity to be invalid or unenforceable, in whole or in part, that provision shall be construed or limited in such a way as to make it enforceable, consistent with the manifest intentions of the parties. If such a construction or limitation is not possible, the unenforceable provision will be stricken, and the remaining provisions of this Agreement will remain valid and enforceable.

18. Waiver

Failure by either party to insist upon the strictest performance or observance of any provision of this Agreement or to exercise any right or remedy arising out of this Agreement shall not be construed as a waiver of any right or remedy with respect to any existing or subsequent breach or default.

19. Notices

Any and all written notices, communications, or payments shall be made to the respective parties at their addresses indicated in the first paragraph of this Agreement or at such other address as a party may indicate in a written notice to the other party to this Agreement.

20. Governing Law.

This Agreement shall be governed by the internal laws of the State of Florida and the parties hereto agree that the courts in the State of Florida shall have exclusive jurisdiction for any claims or disputes which may arise hereunder.

21. Litigation

In the event that enforcement of this Agreement becomes necessary (whether suit be brought or not), the prevailing party shall be entitled to recover, in addition to all other remedies available at law, an amount equal to all costs and expenses incurred in connection with such enforcement, including reasonable attorney's fees at the trial level and in connection with all appellate proceedings.

In the event of any legal or equitable action arising under this Agreement, the parties agree that jurisdiction and venue of such action shall lie exclusively within the state courts of Florida located in Orange County, Florida, or the United States District Court for the Middle District of Florida, Orlando Division, and the parties specifically waive any other jurisdiction and venue.

22. Assignment

Client may not assign this Agreement without the consent of Mojo.

23. Government Requirements

Each party hereto shall comply with all statues, ordinances and government regulations in the conduct of its business.

IN WITNESS WHEREOF, Client and Mojo have duly executed this Contract as of the day and year executed below.

Mojo Interactive

By: _____

Name: _____

Title: _____

Date: _____

Client: Nevvas Eve Associates

By: _____

Name: Herbert J. Nevvas

Title: Director

Date: 6/16/99

http://www.quackwatch.org/00AboutQuackwatch/chd.html
Donations of $1 to $50 to help support Quackwatch can be made through
http://s1.amazon.com/exec/varzea/pay/T1X6GUTTCLU3T4

of which are intended to be later submitted to, or held for inspection by, the Food and Drug Administration as part of an application for a research or marketing permit. The term does not include experiments that must meet the provisions of Part 58, regarding nonclinical laboratory studies. The terms "research," "clinical research," "clinical study," "study," and "clinical investigation" are deemed to be synonymous for purposes of this part.

(d) "Emergency use" means the use of a test article on a human subject in a life-threatening situation in which no standard acceptable treatment is available, and in which there is not sufficient time to obtain IRB approval.

(e) "Human subject" means an individual who is or becomes a participant in research, either as a recipient of the test article or as a control. A subject may be either a healthy individual or a patient.

(f) "Institution" means any public or private entity or agency (including Federal, State, and other agencies). The term "facility" as used in section 520(g) of the act is deemed to be synonymous with the term "institution" for purposes of this part.

(g) "Institutional Review Board (IRB)" means any board, committee, or other group formally designated by an institution to review, to approve the initiation of, and to conduct periodic review of, biomedical research involving human subjects. The primary purpose of such review is to assure the protection of the rights and welfare of the human subjects. The term has the same meaning as the phrase "institutional review committee" as used in section 520(g) of the act.

(h) "Investigator" means an individual who actually conducts a clinical investigation (i.e., under whose immediate direction the test article is administered or dispensed to, or used involving, a subject) or, in the event of an investigation conducted by a team of individuals, is the responsible leader of that team.

(i) "Minimal risk" means that the risks of harm anticipated in the proposed research are not greater, considering probability and magnitude, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

(j) "Sponsor" means a person or other entity that initiates a clinical investigation, but that does not actually conduct the investigation, i.e., the test article is administered or dispensed to, or used involving, a subject under the immediate direction of another individual. A person other than an individual (e.g., a corporation or agency) that uses one or more of its own employees to conduct an investigation that it has initiated is considered to be a sponsor (not a sponsor-investigator), and the employees are considered to be investigators.

(k) "Sponsor-investigator" means an individual who both initiates and actually conducts, alone or with others, a clinical investigation, i.e., under whose immediate direction the test article is administered or dispensed to, or used involving, a subject. The term does not include any person other than an individual, e.g., it does not include a corporation or agency. The obligations of a sponsor-investigator under this part include both those of a sponsor and those of an investigator.

(l) "Test article" means any drug for human use, biological product for human use, medical device for human use, human food additive, color additive, electronic product, or any other article subject to regulation under the act or under sections 351 or 354-360F of the Public Health Service Act.

§56.103 Circumstances in which IRB review is required.

(a) Except as provided in §§56.104 and 56.105, any clinical investigation which must meet the requirements for prior submission (as required in Parts 312, 812, and 813) to the Food and Drug Administration shall not be initiated unless that investigation has been reviewed and approved by, and remains subject to continuing review by, an IRB meeting the requirements of this part.

(b) Except as provided in §§56.104 and 56.105, the Food and Drug Administration may decide not to consider in support of an application for a research or marketing permit any data or information that has been derived from a clinical investigation that has not been approved by, and that was not subject to initial and continuing review by, an IRB meeting the requirements of this part. The determination that a clinical investigation may not be considered in support of an application for a research or marketing permit does not, however, relieve the applicant for such a permit of any obligation under any other applicable regulations to submit the results of the investigation to the Food and Drug Administration.

(c) Compliance with these regulations will in no way render inapplicable pertinent Federal, State, or local laws or regulations.

§56.104 Exemptions from IRB requirement.

The following categories of clinical investigations are exempt from the requirements of this part for IRB review:

(a) Any investigation which commenced before July 27, 1981 and was subject to requirements for IRB review under FDA regulations before that date, provided that the investigation remains subject to review of an IRB which meets the FDA requirements in effect before July 27, 1981.

(b) Any investigation commenced before July 27, 1981 and was not otherwise subject to requirements for IRB review under Food and Drug Administration regulations before that date.

(c) Emergency use of a test article, provided that such emergency use is reported to the IRB within 5 working days. Any subsequent use of the test article at the institution is subject to IRB review.

§56.105 Waiver of IRB requirement.

On the application of a sponsor or sponsor-investigator, the Food and Drug Administration may waive any of the requirements contained in these regulations, including the requirements for IRB review, for specific research activities

or for classes of research activities, otherwise covered by these regulations.

Subpart B — Organization and Personnel

§56.107 IRB membership.

(a) Each IRB shall have at least five members, with varying backgrounds to promote complete and adequate review of research activities commonly conducted by the institution. The IRB shall be sufficiently qualified through the experience and expertise of its members, and the diversity of the members' backgrounds including consideration of the racial and cultural backgrounds of members and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects. In addition to possessing the professional competence necessary to review specific research activities, the IRB shall be able to ascertain the acceptability of proposed research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice. The IRB shall therefore include persons knowledgeable in these areas. If an IRB regularly reviews research that involves a vulnerable category of subjects, including but not limited to subjects covered by other parts of this chapter, the IRB should include one or more individuals who are primarily concerned with the welfare of these subjects.

(b) No IRB may consist entirely of men, or entirely of women, or entirely of members of one profession.

(c) Each IRB shall include at least one member whose primary concerns are in nonscientific areas; for example: lawyers, ethicists, members of the clergy.

(d) Each IRB shall include at least one member who is not otherwise affiliated with the institution and who is not part of the immediate family of a person who is affiliated with the institution.

(e) No IRB may have a member participate in the IRB's initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB.

(f) An IRB may, in its discretion, invite individuals with competence in special areas to assist in the review of complex issues which require expertise beyond or in addition to that available on the IRB. These individuals may not vote with the IRB.

Subpart C — IRB Functions and Operations

§56.108 IRB functions and operations.

In order to fulfill the requirements of these regulations, each IRB shall:

(a) Follow written procedures (1) for conducting its initial and continuing review of research and for reporting its findings and actions to the investigator and the institution, (2) for determining which projects requirereview more often than annually and which projects need verification from sources other than the investigators that no material changes have occurred since previous IRB review, (3) for insuring prompt reporting to the IRB of changes in a research activity, (4) for insuring that changes in approved research, during the period for which IRB approval has already been given, may not be initiated without IRB review and approval except where necessary to eliminate apparent immediate hazards to the human subjects; and (5) for insuring prompt reporting to the IRB of unanticipated problems involving risks to subjects or others.

(b) Except when an expedited review procedure is used (see §56.110), review proposed research at convened meetings at which a majority of the members of the IRB are present, including at least one member whose primary concerns are in nonscientific areas. In order for the research to be approved, it shall receive the approval of a majority of those members present at the meeting.

(c) Be responsible for reporting to the appropriate institutional officials and the Food and Drug Administration any serious or continuing noncompliance by investigators with the requirements and determinations of the IRB.

§56.109 IRB review of research.

(a) An IRB shall review and have authority to approve, require modifications in (to secure approval), or disapprove all research activities covered by these regulations.

(b) An IRB shall require that information given to subjects as part of informed consent is in accordance with §50.25. The IRB may require that information, in addition to that specifically mentioned in §50.25, be given to the subjects when in the IRB's judgment the information would meaningfully add to the protection of the rights and welfare of subjects.

(c) An IRB shall require documentation of informed consent in accordance with §50.27, except that the IRB may, for some or all subjects, waive the requirement that the subject or the subject's legally authorized representative sign a written consent form if it finds that the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside the research context. In cases where the documentation requirement is waived, the IRB may require the investigator to provide subjects with a written statement regarding the research.

(d) An IRB shall notify investigators and the institution in writing of its decision to approve or disapprove the proposed research activity, or of modifications required to secure IRB approval of the research activity. If the IRB decides to disapprove a research activity, it shall include in its written notification a statement of the reasons for its decision and give the investigator an opportunity to respond in person or in writing.

(e) An IRB shall conduct continuing review of research covered by these regulations at intervals appropriate to the degree of risk, but not less than once per year, and shall have authority to observe or have a third party observe the consent process and the research.

§56.110 Expedited review procedures for certain kinds of research involving no more than minimal risk, and for minor changes in approved research.

(a) The Food and Drug Administration has established, and published in the FEDERAL REGISTER, a list of categories of research that may be reviewed by the IRB through an expedited review procedure. The list will be amended, as appropriate, through periodic republication in the FEDERAL REGISTER.

(b) An IRB may review some or all of the research appearing on the list through an expedited review procedure, if the research involves no more than minimal risk. The IRB may also use the expedited review procedure to review minor changes in previously approved research during the period for which approval is authorized. Under an expedited review procedure, the review may be carried out by the IRB chairperson or by one or more experienced reviewers designated by the chairperson from among members of the IRB. In reviewing the research, the reviewers may exercise all of the authorities of the IRB except that the reviewers may not disapprove the research. A research activity may be disapproved only after review in accordance with the non-expedited procedure set forth in §56.108(b).

(c) Each IRB which uses an expedited review procedure shall adopt a method for keeping all members advised of research proposals which have been approved under the procedure.

(d) The Food and Drug Administration may restrict, suspend, or terminate an institution's or IRB's use of the expedited review procedure when necessary to protect the rights or welfare of subjects.

§56.111 Criteria for IRB approval of research.

(a) In order to approve research covered by these regulations the IRB shall determine that all of the following requirements are satisfied:

(1) Risks to subjects are minimized: (i) by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and (ii) whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.

(2) Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may be expected to result. In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies that subjects would receive even if not participating in the research). The IRB should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.

(3) Selection of subjects is equitable. In making this assessment, the IRB should take into account the purposes of the research and the setting in which the research will be conducted.

(4) Informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with and to the extent required by Part 50.

(5) Informed consent will be appropriately documented, in accordance with and to the extent required by §50.27.

(6) Where appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.

(7) Where appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

(b) Where some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as persons with acute or severe physical or mental illness, or persons who are economically or educationally disadvantaged, appropriate additional safeguards have been included in the study to protect the rights and welfare of these subjects.

§56.112 Review by institution.

Research covered by these regulations that has been approved by an IRB may be subject to further appropriate review and approval or disapproval by officials of the institution. However, those officials may not approve the research if it has not been approved by an IRB.

§ 56.113 Suspension or termination of IRB approval of research.

An IRB shall have authority to suspend or terminate approval of research that is not being conducted in accordance with the IRB's requirements or that has been associated with unexpected serious harm to subjects. Any suspension or termination of approval shall include a statement of the reasons for the IRB's action and shall be reported promptly to the investigator, appropriate institutional officials, and the Food and Drug Administration.

§56.114 Cooperative research.

In complying with these regulations, institutions involved in multi-institutional studies may use joint review, reliance upon the review of another qualified IRB, or similar arrangements aimed at avoidance of duplication of effort.

Subpart D — Records and Reports

§56.115 IRB records.

(a) An institution, or where appropriate an IRB, shall prepare and maintain adequate documentation of IRB activities, including the following:

(1) Copies of all research proposals reviewed, scientific evaluations, if any, that accompany the proposals, approved sample consent documents, progress reports submitted by investigators, and reports of injuries to subjects.

(2) Minutes of IRB meetings which shall be in sufficient detail to show attendance at the meetings; actions taken by the IRB; the vote on these actions including the number of members voting for, against, and abstaining; the basis for requiring changes in or disapproving research; and a written summary of the discussion of controverted issues and their resolution.

(3) Records of continuing review activities.

(4) Copies of all correspondence between the IRB and the investigators.

(5) A list of IRB members identified by name; earned degrees; representative capacity; indications of experience such as board certifications, licenses, etc., sufficient to describe each member's chief anticipated contributions to IRB deliberations; and any employment or other relationship between each member and the institution; for example: full-time employee, part-time employee, a member of governing panel or board, stockholder, paid or unpaid consultant.

(6) Written procedures for the IRB as required by §56.108(a).

(7) Statements of significant new findings provided to subjects, as required by §50.25.

(b) The records required by this regulation shall be retained for at least 3 years after completion of the research, and the records shall be accessible for inspection and copying by authorized representatives of the Food and Drug Administration at reasonable times and in a reasonable manner.

(c) The Food and Drug Administration may refuse to consider a clinical investigation in support of an application for a research or marketing permit if the institution or the IRB that reviewed the investigation refuses to allow an inspection under this section.

Subpart E — Administrative Actions for Noncompliance

§56.120 Lesser administrative actions.

(a) If apparent noncompliance with these regulations in the operation of an IRB is observed by an FDA investigator during an inspection, the inspector will present an oral or written summary of observations to an appropriate representative of the IRB. The Food and Drug Administration may subsequently send a letter describing the noncompliance to the IRB and to the parent institution. The agency will require that the IRB or the parent institution respond to this letter within a time period specified by FDA and describe the corrective actions that will be taken by the IRB, the institution, or both to achieve compliance with these regulations.

(b) On the basis of the IRB's or the institution's response, FDA may schedule a reinspection to confirm the adequacy of corrective actions. In addition, until the IRB or the parent institution takes appropriate corrective action, the agency may:

(1) Withhold approval of new studies subject to the requirements of this part that are conducted at the institution or reviewed by the IRB;

(2) Direct that no new subjects be added to ongoing studies subject to this part;

(3) Terminate ongoing studies subject to this part when doing so would not endanger the subjects; or

(4) When the apparent noncompliance creates a significant threat to the rights and welfare of human subjects, notify relevant State and Federal regulatory agencies and other parties with a direct interest in the agency's action of the deficiencies in the operation of the IRB.

(c) The parent institution is presumed to be responsible for the operation of an IRB, and the Food and Drug Administration will ordinarily direct any administrative action under this subpart against the institution. However, depending on the evidence of responsibility for deficiencies, determined during the investigation, the Food and Drug Administration may restrict its administrative actions to the IRB or to a component of the parent institution determined to be responsible for formal designation of the IRB.

§56.121 Disqualification of an IRB or an institution.

(a) Whenever the IRB or the institution has failed to take adequate steps to correct the noncompliance stated in the letter sent by the agency under §56.120(a), and the Commissioner of Food and Drugs determines that this noncompliance may justify the disqualification of the IRB or of the parent institution, the Commissioner will institute proceedings in accordance with the requirements for a regulatory hearing set forth in Part 16.

(b) The Commissioner may disqualify an IRB or the parent institution if the Commissioner determines that:

1) The IRB has refused or repeatedly failed to comply with any of the regulations set forth in this part, and

(2) The noncompliance adversely affects the rights or welfare of the human subjects in a clinical investigation.

(c) If the Commissioner determines that disqualification is appropriate, the Commissioner will issue an order that explains the basis for the determination and that prescribes any actions to be taken with regard to ongoing clinical research conducted under the review of the IRB. The Food and Drug Administration will send notice of the disqualification to the IRB and the parent institution. Other parties with a direct interest, such as sponsors and clinical investigators, may also be sent a notice of the disqualification. In addition, the agency may elect to publish a notice of its action in the FEDERAL REGISTER.

(d) The Food and Drug Administration will not approve an application for a research permit for a clinical investigation that is to be under the review of a disqualified IRB or that is to be conducted at a disqualified institution, and it may refuse to consider in support of a marketing permit the data from a clinical investigation that was reviewed by a disqualified IRB as conducted at a disqualified institution, unless the IRB or the parent institution is reinstated as provided in §56.123.

§56.122 Public disclosure of information regarding revocation.

A determination that the Food and Drug Administration has disqualified an institution and the administrative record

regarding that determination are disclosable to the public under Part 20.

§56.123 Reinstatement of an IRB or an institution.

An IRB or an institution may be reinstated if the Commissioner determines, upon an evaluation of a written submission from the IRB or institution that explains the corrective action that the institution or IRB plans to take, that the IRB or institution has provided adequate assurance that it will operate in compliance with the standards set forth in this part. Notification of reinstatement shall be provided to all persons notified under §56.121(c).

§56.124 Actions alternative or additional to disqualification.

Disqualification of an IRB or of an institution is independent of, and neither in lieu of nor a precondition to, other proceedings or actions authorized by the act. The Food and Drug Administration may, at any time, through the Department of Justice institute any appropriate judicial proceedings (civil or criminal) and any other appropriate regulatory action, in addition to or in lieu of, and before, at the time of, or after, disqualification. The agency may also refer pertinentmatters to another Federal, State, or local government agency for any action that that agency determines to be appropriate.

Exhibit C

Schulman Associates
Institutional Review Board, Inc.
IRB

John M. Isidor, J.D., Chairman
Alan A. Schulman, J.D., Vice-Chairman
Jonathan Singer, M.D., Vice-Chairman

APPROVED: 08-20-97
EXPIRATION DATE: 08-19-98

August 27, 1997

FROM:	Schulman Associates Institutional Review Board, Inc. (SAIRB)
TO:	Herbert J. Nevyas, M.D./Anita Nevyas-Wallace, M.D. – Bala Cynwyd, PA
SUBJECT:	Protocol and Informed Consent
SPONSOR:	Nevyas Eye Associates
PROTOCOL NO:	NEV-97-001

At a meeting of the Institutional Review Board of August 20, 1997, the Board reviewed the informed consent and protocol entitled:

LASIK with an Excimer Laser in the Surgical Treatment of Refractive Errors: Myopia with or without Astigmatism

This letter is to inform you that the Board has approved the revised protocol dated July 19, 1997, and the enclosed IRB stamped informed consent. You must use only the enclosed "SAIRB Approved" informed consent. We have included a copy of the most current Board membership list to maintain with your study binder.

Under FDA regulations, this approval will last only one year. If the study is expected to last beyond a year, you must request re-approval for the next year at least 4 weeks prior to the expiration date noted above. Please use the enclosed Report Form and indicate if six month, annual, or final report. Your first report to the Board on the status of this study is due six months from the approval date or at the time the study closes, whichever is earlier.

The FDA requires you to notify the IRB of any new advertisements or recruiting material, serious adverse events, amendments or changes in the protocol, significant protocol deviations, patient death or termination of the study. Please note that you must submit all protocol amendments and/or advertisements to the Board for review, and await a response from the Board, prior to implementing the amendments and/or advertisements.

Schulman Associates Institutional Review Board, Inc. is in compliance with the regulations of the Food and Drug Administration as described in 21 CFR parts 50 and 56.

Sincerely,

John M. Isidor, J.D., Chairman
Schulman Associates Institutional Review Board, Inc.

JMI/jab
Enclosures

cc: Dr. Barbara Fant

PLEASE USE OUR IRB #97-1942-0 ON ALL CORRESPONDENCE FOR THIS STUDY.

NYA 000024

10 Knollcrest Drive, Suite 300 Cincinnati, Ohio 45237 Phone: (513) 761-4100 Fax (513) 761-5546

Schulman Associates
Institutional Review Board, Inc.
IRB

John M. Isidor, J.D., Chairman
Alan A. Schulman, J.D., Vice-Chairman
Julie Waltz Gerlach, B.S.N., M.P.H., Vice-Chairman

July 17, 1998

FROM: Schulman Associates Institutional Review Board, Inc.
TO: Herbert J. Nevyas, M.D.
SUBJECT: **Amendment 1 dated 12-4-97, Protocol Version 1.2 dated July 8, 1998 Consent forms for LASIK retreatment surgery, LASIK fellow eye surgery on different days, LASIK fellow eye surgery on the same day**
SPONSOR: Herbert J. Nevyas, M.D.
PROTOCOL NO.: NEV-97-001

The Board has received Barbara Fant's letter dated July 8, 1998, regarding the above-referenced protocol.

This letter is to inform you that the Board, at its meeting of July 15, 1998, reviewed and approved Amendment 1 dated 12-4-97 and Protocol Version 1.2 dated July 8, 1998. The Board has also approved the consents for the LASIK retreatment surgery and the LASIK fellow eye surgery on different days. The consent form for the LASIK fellow eye surgery on the same day is approved, as revised; the Board felt a more complete consent form was necessary. Enclosed are "SAIRB Approved" copies of the above listed consent forms dated July 17, 1998.

Sincerely,

John M. Isidor, J.D., Chairman
Schulman Associates Institutional Review Board, Inc.

JMI/lh

Enclosure

cc: Barbara Fant, Pharm.D.

PLEASE REFERENCE OUR IRB #97-1942-0 ON ALL CORRESPONDENCE FOR THIS STUDY

NYA 00049

10 Knollcrest Drive, Suite 200 Cincinnati, Ohio 45237 Phone: (513) 761-4100 Fax (513) 761-5546

Nevyas Eye Associates / Delaware Valley Laser Surgery Institute
Ambulatory Surgery Center

Herbert J. Nevyas, M.D.
Refractive, Cataract, and Corneal Surgery

Joann Y. Nevyas, M.D.
Cataract and Glaucoma Surgery and Therapy

Anita Nevyas-Wallace, M.D.
Refractive, Cataract, and Corneal Surgery

Ira B. Wallace, M.D.
Ophthalmic Plastic and Reconstructive Surgery, Cosmetic Surgery

Edward A. Deglin, M.D.
Vitreo-retinal Disease and Surgery

Mitchell E. Stein, M.D.
Retinal Disease, Glaucoma Medical and Surgical Ophthalmology

Rick S. Choe, M.D.
Glaucoma Surgery and Therapy, Cataract Medical and Surgical Ophthalmology

Bari M. Brandt, M.D.
Vitreo-retinal Disease

Richard H. Sterling, O.D.
Interprofessional Relations Refractive Surgery Coordinator

FAX COVER SHEET

DATE: 10-9-98

TO: Barbara Fast, PhD

FAX: 513-751-3773

PHONE:

RE: Concerning Dr's

FROM: Rich Sterling OD

FAX: [610] 668-1509 BALA CYNWYD OFFICE

PAGES [including cover sheet]: 9

COMMENTS:

☐ URGENT ☑ REVIEW ☐ REPLY

Please note that the information contained in this transmission is confidential in nature. The information is to be used for its intended purpose only and is to be destroyed after the stated need has been fulfilled. This information is not for disclosure. Please deliver immediately to the individual indicated above. If you have received this transmission in error, please notify us immediately by phone and destroy the transmitted documents.

NYA 00074

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nevyas@aol.com

☐ Two Bala Plaza
333 East City Avenue
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Fax 610-668-1509

☐ 20th Floor
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215-561-1411
Fax 215-564-0052

☐ Central Square
2465 Grant Avenue
Philadelphia, PA 19114
215-673-2020
Fax 215-969-6375

☐ 1001-E Lincoln Drive West
Greentree Executive Campus
Marlton, NJ 08053
609-985-9797
Fax 609-985-1191

Dear Barbara:

I simply listed the OD's that have comanaged cases from the list of Post-op visits doctors in the McDonald software:

Frank Angelini, OD	Victor Barouh, OD	Steven Berger, OD
Bruce Block, OD	John Boscia, OD	Jeffrey Brooks, OD
Jeffrey Brosof, OD	Peter Campanella, OD	Leon Candeub, OD
Joan Cirbus, OD	Alan Citrenbaum, OD	Alan Cohen, OD
Paul Cohen, OD	Kevin Corcoran, OD	William Dent, OD
Paul Difiore, OD	William DiMino, OD	Valerie DiPietro-Longo, OD
Peggy Dixon, OD	Peter Dodge, OD	Jeffrey Eidman, OD
Gary Finnegan, OD	Richard Floyd, OD	Stephen Galanter, OD
Joseph Gallagher, OD	Philip Gerson, OD	Robert Ginsburg, OD
Jeffrey Gold, OD	Leroy Goldfarb, OD	Randolph Greber, OD
Donald Hartranft, OD	Jack Hauler, OD	Stephen Hersh, OD
William Jacobson, OD	Martin Kalish, OD	Michelle Kaller, OD
Barry Kanofsky, OD	Michael Karliner, OD	Jerry Kasrel, OD
Martin Kitagawa, OD	Glenn Knezich, OD	Daniel Kramer, OD
Janice Kulba, OD	Roslyn, Kushner, OD	Richard Lawver, OD
Robert Levy, OD	Michael Maizel, OD	Raymond Mancuso, OD
Kimberly McClure, OD	Jonia Mekel, OD	Edward Melman, OD
Morse Michels, OD	Robert Mintz, OD	Benson Olenick, OD
Carl Pecorara, OD	Gary Poole, OD	James Prate, OD
Barry Preiss, OD	Harry Prihar, OD	Raymond Puzio, OD
Louis Reardon, OD	John Renyo, OD	Alan Rosenberg, OD
Jerry Rosenfeld, OD	Harvery Rosenwasser, OD	Alan Roth, OD
Robin Sapossnek, OD	Renny Sardella, OD	Mark Schnitzel, OD
Ronald Shane, OD	Deborah Signorino, OD	Steven Simmerman, OD
Stephen Sinoway, OD	Harry Snyder, OD	Robert Spivack, OD
Mervin Stoltzfus, OD	Joan Storer, MD	Paul Suscavage, OD
Sam Tilonsky, OD	Richard Weiner, OD	Arnold Witkin, OD
Robert Wortman, OD	Samuel Young, OD	

In addition to the above names we have a group of OD's, Delaware Valley Refractive Surgery Partnership that was formed specifically to comanage refractive pts.. In other words they are also "potential" comanaging doctors. As you see I've enclosed names, no addresses, if you need that let me know.

Rich

5-7-98

Drs.:

The enclosed represents all the patients who have had LASIK since the IDE submission. The total is 25 high myopes (as defined by FDA >-6.75D) and 53 low myopes.

As mentioned before as of 5-6-98 Barbara Fant, PhD had not submitted our enhancements to the FDA, she has though put us first on her to do list.

Rich

REPORT OF LASIK PROCEDURES FOR NEVYAS MODEL SULLIVAN EXCIMER LASER
RE: G970088/S2, S3 AND S4

INVESTIGATOR	ID#	EYE	DATE	SPH./CYL	PRIMARY	FELLOW	ENH. PRE-IDE	ENH.-IDE
HJN	63086	OD	8/28/97	-3.25-5.00x26"	X			
HJN	63086	OS	8/28/97	-4.75-3.00x167"		X		
HJN	64118	OS	8/28/97	-2.50-2x175"		X		
HJN	64611	OD	8/28/97	-4.00-0.50x133"		X		
HJN	64611	OS	8/28/97	-3.50-0.75x180	X			
HJN	64712	OS	8/28/97	-6.75-0.75x170		X		
ANW	62658	OS	8/28/97	-2.00-1.25x123			X	
ANW	60816	OD	8/28/97	-1.00-2.50x105"			X	
HJN	64712	OD	9/11/97	-6.75-1.25x180"	X			
HJN	63828	OD	9/11/97	-7.75-1.00x180"		X		
HJN	64070	OS	9/11/97	-12.00-0.75x150		X		
HJN	64973	OS	9/11/97	-2.75-1.00x165	X			
HJN	64118	OD	9/11/97	-0.75-2.50x165"	X			
HJN	58377	OS	9/11/97	-3.50-2.00x154"			X	
HJN	62610	OD	9/11/97	PL-2.00x87			X	
HJN	64969	OS	9/11/97	-6.50-1.00x180"	X			
ANW	57726	OD	9/11/97	-1.50sphere"	X			
HJN	58908	OS	9/25/97	+3.50-1.00x80"			X	
ANW	65180	OS	9/25/97	-3.75-1.25x180"		X		
ANW	62514	OD	9/25/97	-1.25sphere			X	
HJN	64532	OS	10/7/97	-13.00-0.50x135"		X		
HJN	65251	OS	10/9/97	-7.25-0.50x63		X		
HJN	65280	OS	10/9/97	-3.50-0.50x2"		X		

REPORT OF LASIK PROCEDURES FOR NEVYAS MODEL SULLIVAN EXCIMER LASER
RE: G970088/S2, S3 AND S4

HJN	64532	OD	10/9/97	-11.50-1.00x10"	X			
HJN	64657	OS	10/9/97	-8.50-1.00x158"	X			
HJN	64411	OS	10/9/97	-7.75-2.75x170"		X		
ANW	65180	OD	10/9/97	-3.25-2.00x166"	X			
HJN	64657	OD	10/23/97	-8.00-1.25x175"		X		
HJN	64892	OS	10/23/97	-3.75-2.50x10"		X		
HJN	61604	OS	10/23/97	-8.25-2.25x115"		X		
HJN	65251	OD	10/23/97	-7.50 sphere"	X			
HJN	65280	OD	10/23/97	-3.75-0.50x153"	X			
HJN	64941	OS	11/13/97	-6.25-0.50x90"		X		
HJN	64892	OD	11/13/97	-2.75-1.50x170	X			
HJN	65212	OS	11/13/97	-11.00-0.75x165"		X		
HJN	62117	OS	11/13/97	-1.75-0.50x95"			X	
ANW	65607	OD	11/13/97	-2.75-0.25x175"		X		
ANW	65459	OD	11/13/97	-4.00-1.50x110"		X		
HJN	65890	OS	12/4/97	-7.00 sphere"	X			
HJN	65212	OD	12/4/97	-10.75-1.00x180	X			
HJN	65489	OD	12/4/97	-4.50-0.50x180		X		
HJN	64941	OD	12/4/97	-6.00-0.50x93"	X			
HJN	66033	OD	12-4-97	-12.00-3.50x14"		X		
HJN	65701	OD	12/4/97	-3.75-0.25x150"		x		
ANW	65615	OD	12/4/97	-10.00-1.25x170"		X		
ANW	61798	OD	12/4/97	-2.25-1.25x130"		X		

REPORT OF LASIK PROCEDURES FOR NEVYAS MODEL SULLIVAN EXCIMER LASER
RE: G970088/S2, S3 AND S4

ANW	65607	OS	12/4/97	-2.50 sphere"	X			
ANW	57385	OD	12/4/97	-2.00-0.50x91"	X			
ANW	66068	OS	12/4/97	-7.00-1.75x167"		X		
ANW	65724	OS	12/4/97	-4.50-0.25x25		X		
HJN	59885	OD	12/11/97	-2.00-0.50x60"	X			
HJN	65489	OS	12/11/97	-4.25-0.50x180"	X			
ANW	65459	OS	12/11/97	-4.50-0.75x93"	X			
ANW	61798	OS	12/11/97	"-3.25-1.25x100	X			
ANW	65615	OS	12/11/97	-8.00-3.00x175"	X			
ANW	65724	OD	12/11/97	-4.00-0.75x148"	X			
ANW	66068	OD	12/11/97	-7.25-1.00x15"	X			
ANW	65322	OS	01/08/98	"-8.00-1.25x167		X		
HJN	65890	OD	01/08/98	-6.75 sphere	X			
HJN	50547	OS	01/08/98	"-11.00-.50x130		X		
HJN	63622	OD	01/08/98	-1.50-2.50x3	X			
HJN	63828	OS	01/08/98	-1.25-0.75x135			X	
ANW	66350	OS	01/08/98	-3.75-0.75x5		X		
ANW	65408	OS	01/08/98	-10.50-0.75X169		X		
ANW	65408	OD	1/12/98	-10.25-1.25X180	X			
ANW	66591	OS	01/20/98	-9.25-1.25X160		X		
ANW	66350	OD	1/20/98	-4.00-0.50X148	X			
ANW	65322	OD	1/20/98	-7.75-1.25X48	X			
HJN	66746	OS	1/29/98	-3.00-0.75X180		X		

REPORT OF LASIK PROCEDURES FOR NEVYAS MODEL SULLIVAN EXCIMER LASER
RE: G970088/S2, S3 AND S4

HJN	66236	OS	1/29/98	-14.25-2.00X172		X		
HJN	66591	OD	1/29/98	-10.00-1.00X35	X			
HJN	64520	OD	1/29/98	-0.50-1.75X21	X			
HJN	50547	OD	1/29/98	-10.75-0.25X180	X			
HJN	60618	OD	1/29/98	-1.50-0.50X178			X	
HJN	65843	OD	2/19/98	-3.75SPHERE		X		
HJN	66746	OD	2/19/98	-3.00SPHERE	X			
HJN	66346	OS	2/19/98	-8.00-1.00X180		X		
HJN	66236	OD	2/19/98	-13.00-1.50X30	X			
HJN	65481	OS	2/19/98	-4.00-0.25X180		X		
HJN	34389	OD	2/19/98	-3.50-3.25X165		X		
HJN	66385	OS	2/19/98	-9.75-1.75X4		X		
HJN	59885	OS	2/19/98	-2.75-0.25X120		X		
HJN	66940	OS	2/19/98	-5.75 SPHERE		X		
ANW	58377	OS	2/19/98	PL-4.00X162			X	
ANW	66784	OD	2/19/98	-4.50-2.00X80	X			
ANW	66647	OD	2/19/98	-4.50-0.50X113		X		
ANW	66678	OS	2/19/98	-5.50-0.25X165		X		
ANW	66053	OS	2/19/98	-8.00-0.25X6		X		
ANW	66678	OD	2/26/98	-6.00-0.50X13	X			
ANW	66647	OS	2/26/98	-4.25-0.50X60	X			
ANW	66053	OD	2/26/98	-7.00-0.25X30	X			
HJN	65843	OS	2/26/98	-3.75-0.50X180	X			

REPORT OF LASIK PROCEDURES FOR NEVYAS MODEL SULLIVAN EXCIMER LASER
RE: G970088/S2, S3 AND S4

HJN	65481	OD	2/26/98	-4.00 SPHERE	X			
HJN	66385	OD	2/26/98	-10.25-2.50X13	X			
HJN	67025	OS	2/26/98	-8.00-1.00X176		X		
HJN	66884	OS	2/26/98	-6.00-1.00X180		X		
HJN	66940	OD	2/26/98	-6.50SPHERE	X			
HJN	66033	OS	2/26/98	-10.50-2.50X180	X			
HJN	67206	OS	3/12/98	"-7.00-0.50X110		X		
HJN	67025	OD	3/12/98	"-7.75-0.50X160	X			
HJN	66879	OS	3/12/98	"-6.00-4.00X165		X		
HJN	66346	OD	3/12/98	"-7.00-1.75X168	X			
HJN	67230	OS	3/12/98	"-4.00 SPHERE		X		
HJN	67466	OS	3/12/98	"-8.75-0.25X145		X		
HJN	66920	OD	3/12/98	"-3.50-2.25X180		X		
HJN	67429	OS	3/12/98	"-2.50 SPHERE		X		
ANW	66943	OD	3/12/98	"-6.50-1.25X58		X		
ANW	66508	OS	3/12/98	"-5.00-0.50X95		X		
HJN	67206	OD	3/19/98	"-7.25-0.50X40	X			
HJN	67879	OD	3/19/98	"-4.75-5.00X3	X			
HJN	67230	OD	3/19/98	"-4.00 SPHERE	X			
HJN	67429	OD	3/19/98	"-3.00-0.25X177	X			
HJN	64921	OD	3/19/98	"-10.00-1.50X14		X		
HJN	66884	OD	3/19/98	"PL-2.50X50	X			
HJN	66920	OS	3/19/98	"-4.50-1.75X165	X			

REPORT OF LASIK PROCEDURES FOR NEVYAS MODEL SULLIVAN EXCIMER LASER
RE: G970088/S2, S3 AND S4

HJN	62581	OS	3/19/98	"-9.75-0.75X100		X		
HJN	67466	OD	3/19/98	"-9.50-1.25X164	X			
ANW	67608	OS	3/19/98	"-4.25-1.00X164		X		
ANW	66508	OD	3/19/98	"-4.50 SPHERE	X			
ANW	66943	OS	3/19/98	"-9.00-0.75X176	X			
ANW	67608	OD	3/19/98	"-4.00-1.00X180	X			
HJN	65701	OS	4/9/98	"-5.00-0.50X90	X			
HJN	67643	OS	4/9/98	"-3.75-2.25X160		X		
HJN	67520	OD	4/9/98	"-1.50-0.75X90		X		
HJN	62581	OD	4/9/98	"-9.75-0.25X97	X			
HJN	67526	OS	4/9/98	"-4.25-0.25X110		X		
HJN	67946	OS	4/9/98	"-5.25-0.50X180		X		
HJN	67567	OS	4/9/98	"-6.75 SPHERE		X		
HJN	67770	OS	4/9/98	"-1.50-1.25X175		x		
HJN	67946	OD	4/9/98	"-5.00 SPHERE	X			
HJN	67512	OD	4/9/98	"-7.50-0.50X58		X		
ANW	64401	OD	4/9/98	"-4.75-0.50X157		X		
ANW	67310	OS	4/9/98	"-8.50-0.75X151		X		
ANW	64401	OS	4/9/98	"-4.50-0.50X171	X			
ANW	67392	OS	4/9/98	"-5.75 SPHERE		X		
HJN	67849	OS	4/23/98	"-3.25-0.75X75		X		
HJN	66039	OD	4/23/98	"-5.00 SPHERE		X		
HJN	67386	OS	4/23/98	"-7.50-0.25X90		X		
HJN	67971	OD	4/23/98	"-1.00-1.00X150		X		
HJN	64921	OS	4/23/98	"-9.75-1.25X90	X			

REPORT OF LASIK PROCEDURES FOR NEVYAS MODEL SULLIVAN EXCIMER LASER
RE: G970088/S2, S3 AND S4

HJN	67526	OD	4/23/98	"-4.25-0.25X90	X			
HJN	68038	OD	4/23/98	"-6.25-0.25X160		X		
HJN	67643	OD	4/23/98	"-4.00-2.00X40	X			
HJN	67596	OD	4/23/98	"-4.75-0.75X90		X		
HJN	68038	OS	4/23/98	"-6.00-0.50X125	X			
HJN	67567	OD	4/23/98	"-6.75 SPHERE	X			
HJN	67947	OS	4/23/98	"-4.75-0.25X25		X		
ANW	67310	OD	4/23/98	"-8.75-2.00X22	X			
ANW	67530	OD	4/23/98	"-5.00-0.25X164		X		
ANW	67392	OD	4/23/98	"-6.75 SPHERE	X			
ANW	67256	OS	4/23/98	"-4.25-2.00X11		X		
HJN	67947	OD	4/30/98	"-4.25-0.25X135	X			
HJN	67849	OD	4/30/98	"-3.25-0.50X105	X			
HJN	66421	OD	4/30/98	"-2.00-0.75X135		X		
HJN	67386	OD	4/30/98	"-7.50-0.25X90	X			
HJN	66421	OS	4/30/98	"-1.25-0.25X10	X			
HJN	67971	OS	4/30/98	"-1.25-2.00X60	X			
HJN	67770	OD	4/30/98	"-1.50-1.00X15	X			
HJN	67596	OS	4/30/98	"-6.50-1.00X70	X			
HJN	66039	OS	4/30/98	"-4.50-1.25X165	X			
HJN	67981	OS	4/30/98	"-5.50-4.25X5		X		
ANW	67530	OS	4/30/98	"-4.75 SPHERE	X			
ANW	67256	OD	4/30/98	"-4.25-2.00X170	X			

12-12-97

Dr. Nevyas:

This is what I submitted to Barbara Fant, PhD as she requested. The columns marked Primary and Fellow correspond to the number of patients that have had monovision (fellow) or those that had distance eye done since conditional approval (there are a 2 pts. that are distance eyes that had only one eye done). I found that so far we have done **17 eyes over -6.75** sphere with **seven patients being considered primary eyes** over -6.75. Those patients that had surgery on "the other eye" prior to 8-28-97 conditional approval are considered fellow eyes for these purposes.

I spoke with Dr. Ronald Shane (OD in Sunbury who sent Nevin Garrett for LASIK) about the possibility of "marketing" his area for refractive surgery. Sunbury is 52 miles outside of Harrisburg. The doctors in his area send their work to Harrisburg where there are two groups doing LASIK (Chottiner and another). In addition Lancaster ophthalmologists have been marketing the Harrisburg and surrounding area. Dr. Shane told me he just got the letter from Kremer so he is aware of his efforts. He said he will send to you when he can, and he talks up your practice all the time, because of his relationship with your Dad and his impression of you and your philosophy.

Rich

REPORT OF LASIK P[illegible]URES FOR NEVYAS MOL[illegible]ULLIVAN E[illegible]R LASER
RE: G970088/S2, S3 AND S[illegible].

INVESTIGATOR	ID#	EYE	DATE	SPH./CYL	PRIMARY	FELLOW	ENH. PRE-IDE	ENH.-IDE
HJN	63086	OD	8/28/97	-3.25-5.00x26"	X			
HJN	63086	OS	8/28/97	-4.75-3.00x167"		X		
HJN	64118	OS	8/28/97	-2.50-2x175"		X		
HJN	64611	OD	8/28/97	-4.00-0.50x133"		X		
HJN	64611	OS	8/28/97	-3.50-0.75x180	X			
HJN	64712	OS	8/28/97	-6.75-0.75x170		X		
ANW	62658	OS	8/28/97	-2.00-1.25x123			X	
ANW	60816	OD	8/28/97	-1.00-2.50x105"			X	
HJN	64712	OD	9/11/97	-6.75-1.25x180"	X			
HJN	63828	OD	9/11/97	-7.75-1.00x180"		X		
HJN	64070	OS	9/11/97	-12.00-0.75x150		X		
HJN	64973	OS	9/11/97	-2.75-1.00x165	X			
HJN	64118	OD	9/11/97	-0.75-2.50x165"	X			
HJN	58377	OS	9/11/97	-3.50-2.00x154"			X	
HJN	62610	OD	9/11/97	PL-2.00x87			X	
HJN	64969	OS	9/11/97	-6.50-1.00x180"	X			
ANW	57726	OD	9/11/97	-1.50sphere"	X			
HJN	58908	OS	9/25/97	+3.50-1.00x80"			X	
ANW	65180	OS	9/25/97	-3.75-1.25x180"		X		
ANW	62514	OD	9/25/97	-1.25sphere			X	
HJN	64532	OS	10/7/97	-13.00-0.50x135"		X		
HJN	65251	OS	10/9/97	-7.25-0.50x63		X		
HJN	65280	OS	10/9/97	-3.50-0.50x2"		X		

REPORT OF LASIK PRO[illegible]JRES FOR NEVYAS MODEL [illegible]IVAN EX[illegible] LASER
RE: G970088/S2, S3 AND S4

HJN	64532	OD	10/9/97	-11.50-1.00x10"	X			
HJN	64657	OS	10/9/97	-8.50-1.00x158"	X			
HJN	64411	OS	10/9/97	-7.75-2.75x170"		X		
ANW	65180	OD	10/9/97	-3.25-2.00x166"	X			
HJN	64657	OD	10/23/97	-8.00-1.25x175"		X		
HJN	64892	OS	10/23/97	-3.75-2.50x10"		X		
HJN	61604	OS	10/23/97	-8.25-2.25x115"		X		
HJN	65251	OD	10/23/97	-7.50 sphere"	X			
HJN	65280	OD	10/23/97	-3.75-0.50x153"	X			
HJN	64941	OS	11/13/97	-6.25-0.50x90"		X		
HJN	64892	OD	11/13/97	-2.75-1.50x170	X			
HJN	65212	OS	11/13/97	-11.00-0.75x165"		X		
HJN	62117	OS	11/13/97	-1.75-0.50x95"			X	
ANW	65607	OD	11/13/97	-2.75-0.25x175"		X		
ANW	65459	OD	11/13/97	-4.00-1.50x110"		X		
HJN	65890	OS	12/4/97	-7.00 sphere"	X			
HJN	65212	OD	12/4/97	-10.75-1.00x180	X			
HJN	65489	OD	12/4/97	-4.50-0.50x180		X		
HJN	64941	OD	12/4/97	-6.00-0.50x93"	X			
HJN	66033	OD	12-4-97	-12.00-3.50x14"		X		
HJN	65701	OD	12/4/97	-3.75-0.25x150"	X			
ANW	65615	OD	12/4/97	-10.00-1.25x170"		X		
ANW	61798	OD	12/4/97	-2.25-1.25x130"		X		

ANW	65607	OS	12/4/97	-2.50 sphere"	X			
ANW	57385	OD	12/4/97	-2.00-0.50x91"	X			
ANW	66068	OS	12/4/97	-7.00-1.75x167"		X		
ANW	65724	OS	12/4/97	-4.50-0.25x25		X		
HJN	59885	OD	12/11/97	-2.00-0.50x60"	X			
HJN	65489	OS	12/11/97	-4.25-0.50x180"	X			
ANW	65459	OS	12/11/97	-4.50-0.75x93"	X			
ANW	61798	OS	12/11/97	"-3.25-1.25x100	X			
ANW	65615	OS	12/11/97	-8.00-3.00x175"	X			
ANW	65724	OD	12/11/97	-4.00-0.75x148"	X			
ANW	66068	OD	12/11/97	-7.25-1.00x15"	X			

Subj: **BSCVA Loss Case Summaries**
Date: 8/5/02 1:25:15 PM Eastern Daylight Time
From: BSFant
To: Nevyas

File: Case Summaries 2 or More Lines of BCVA.doc (120832 bytes)
DL Time (TCP/IP): < 1 minute

Rich,
Attached is a Word document that contains the draft case summaries for eyes treated with the Nevyas laser that had a 2 line or more loss in BSCVA at 6 months or greater postop. At the beginning of the document are 2 tables -- the first is an alphabetical listing of the patients and the second is a listing by surgery ID number of the cases included in the summaries. The summaries contain all the pertinent information that is in the database. Please review the charts for each and add (or have Herb/Anita add) any other explanatory information. We should have a conclusion for each regarding the BSCVA loss. I've written some -- please make sure my comments are reflective of your opinion(s). I've also highlighted in yellow some things that need to be checked. I would like to have these back by the end of this week if possible to forward to FDA.

Thanks,

Barbara S. Fant, Pharm.D.
Clinical Research Consultants, Inc.
3307 Clifton Avenue
Cincinnati, Ohio 45220

PH: (513)-961-8200 FAX: (513)-961-2858

Dear Barb:
In this e-mail I'll respond to your 8/5/02 e-mail regarding 2 line or more loss in BSCVA. I've reviewed all the charts (except Dominic Morgan and Keith Wills) and I'll summarize for you those that need editing. First of all most of the MR or manifest refractions are written incorrectly (e.g. -7.75x-1.50x7 should be -7.75-1.50x7, no x after sphere).
1. (J-T)261- He was 53 years of age at surgery. His preop UCVA was 20/1000 and his MR was -7.25-1.00x4. At the 1/27/01 visit (~4 years) his BSCVA was 20/30 +3.
2. (J-W)325- The last sentence should read -1.50-1.25x90 but it was actually -1.25-1.00x45 which was BSCVA of 20/25+2 and UCVA 20/40+3.
3. (S-E)347- OD preop was actually -12.00-3.50x14. About the 6th line down should be +1.25-1.00x10 and the next to the last line should be +2.25-1.25x45
4. (L-W) 825/826- The sentence that begins with At 6 months... should be +1.75--1.25x135.
5. (M-N) 928- Preop BSCVA was 20/20-. On the last line it should be -1.00-0.50x110 with UCVA of 20/30+3 and BSCVA of 20/20-.
6. (J-R) 1037- About the 5th line down should be MR of -6.50-0.50x103
7. (R-S)1235- BSCVA at 24 months and the MR was -0.50-1.25x133 which yielded 20/25+ BSCVA
8. (L-A) 1236- 6 month visit MR was PL-1.75x170 and at 9 months MR was +0.50-2.50x175
9. (Y-V) 1288 Patient moved to Minnesota lost to followup
10. (A-B) 1529 Last sentence should be +0.75-0.25x110
11. (H-O) 1544 On the next to the last sentence drop the ..."to reverse the monovision".
12. (E-F) 1599-1600 OD is corrected to 20/25 and OS is now -0.75-1.00x165 which gave him 20/20-BSCVA
13. (P-A) 1714- 3rd line should read -7.75-2.00x180
14. (J-K) 1760/1761- At the 3 month postop visit OU had UCVA of 20/20 with the OD MR being -0.50-0.75x45 and OS PL with BCVA of 20/20
15. (J-H) 1949 Pt. has not returned for followup.

To answer your message that I received today regarding the nomogram it is the sphere that determines 17R or 17H not the spherical equivalent.
Rich

~~A-B 1529~~ last selected +0.75 -0.25 x110

~~1 to 1544~~ Both eyes undercorrect (drop the monovision)

E-F ~~1599~~ OD is 20/15 OS is -0.75-1.00 x165 ⇒ 20/20

P-A 1714 - -7.75-2.00 x180

JK 1760/1761 At 3 mos. PO. ~~OD~~ OU had UCVA of 20/20 & MR → OD -0.50-0.75 x45 & OS PL c Bc of

J-H 1949 - Pt. has not returned for followup

* ~~Pt. did not have ke~~

~~L-W 825-826~~ At 6 mos ⊕ 1.75-1.25

NYA 00134

Alphabetical Patient List

Last	First	
Aaron	Linda	
Albert	Regina	
Angstadt	Patricia	
Bagnoli	Al	
Bogdan	Raymond	
Chung	Suk Ling	12/21/01
DeMauriac	Pierre	
Eng	Soo	9/24/01
Ettinger	Jean	
Forstater	Eleanor	
Harlan	Colette	
Hartshorne	Joanne	
Hoerner	Meghan	
Jenson	Tory	
Koenig	Joerg	
Morgan	Dominic	3/27/00 = CANNOT HAVE.
Nester	Michael	
Onofrio	Helen	
Paige	Daniel	
Pavlin	Teresa	
Ring	Jonathan	
Ryan	Cynthia	
Sawn	Walter	8/17/98.
Soper	Robert	
Tumolo	John	
Yang	Yer	
Waddell	Lois	3/8/00
Welty	John	
Wheeler	Chris	
Wills	Keith	9/12/01 = CANNOT HAVE
Yeo	Jacqueline	1/21/02

Patient List Sorted by Surgery ID (order of case summaries)

PatientID	Last	First	SurgeryID	Eye	DateofBirth	SurgeryDate	Age at Surgery	gender
104	Pavlin	Teresa	218	OS	10/1/1953	3/19/1998	44	F
113	Hoerner	Meghan	238	OS	11/7/1969	3/4/1999	29	F
123	Tumolo	John	261	OD	2/12/1944	9/11/1997	54	M
130	Bogdan	Raymond	275	OS	1/24/1950	10/9/1997	48	M
131	Wills	Keith	277	OS	1/26/1958	10/7/1997	40	M
131	Wills	Keith	278	OD	1/26/1958	10/9/1997	40	M

Alphabetical Patient List

Last	First
Aaron	Linda
Albert	Regina
Angstadt	Patricia
Bagnoli	Al
Bogdan	Raymond
Chung	Suk Ling
DeMaurlac	Pierre
Eng	Soo
Ettinger	Jean
Forstater	Eleanor
Harlan	Colette
Hartshorne	Joanne
Hoerner	Meghan
Jenson	Tory
Koenig	Joerg
Morgan	Dominic
Nester	Michael
Onofrio	Helen
Paige	Daniel
Pavlin	Teresa
Ring	Jonathan
Ryan	Cynthia
Sawn	Walter
Soper	Robert
Tumolo	John
Vang	Yer
Waddell	Lois
Welty	John
Wheeler	Chris
Wills	Keith
Yeo	Jacqueline

Patient List Sorted by Surgery ID (order of case summaries)

PatientID	Last	First	SurgeryID	Eye	DateofBirth	SurgeryDate	Age at Surgery	gender
104	Pavlin	Teresa	218	OS	10/1/1953	3/19/1998	44	F
113	Hoerner	Meghan	238	OS	11/7/1969	3/4/1999	29	F
123	Tumolo	John	261	OD	2/12/1944	9/11/1997	54	M
130	Bogdan	Raymond	275	OS	1/24/1950	10/9/1997	48	M
131	Wills	Keith	277	OS	1/26/1958	10/7/1997	40	M
131	Wills	Keith	278	OD	1/26/1958	10/9/1997	40	M

PatientID	Last	First	SurgeryID	Eye	DateofBirth	SurgeryDate	Age at Surgery	gender
149	Welty	John	325	OD	11/5/1948	1/12/1998	49	M
160	Eng	Soo	347	OD	8/30/1961	12/4/1997	36	F
186	Sawn	Walter	407	OS	8/9/1966	4/9/1998	32	M
268	Harlan	Colette	612	OS	3/22/1957	9/10/1998	41	F
361	Waddell	Lois	825	OS	3/4/1959	9/2/1999	40	F
361	Waddell	Lois	826	OD	3/4/1959	9/2/1999	40	F
408	Nester	Michael	928	OS	1/22/1949	5/7/1999	50	M
450	DeMaurlac	Pierre	1019	OS	10/30/1944	8/12/1999	55	M
451	Albert	Regina	1021	OS	6/4/1952	8/12/1999	47	F
451	Albert	Regina	1022	OD	6/4/1952	8/12/1999	47	F
458	Ring	Jonathan	1037	OD	2/27/1977	12/20/1999	23	M
496	Paige	Daniel	1107	OS	12/17/1945	9/17/1999	54	M
496	Paige	Daniel	1108	OD	12/17/1945	9/17/1999	54	M
545	Wheeler	Chris	1191	OS	8/9/1945	12/16/1999	54	M
545	Wheeler	Chris	1192	OD	8/9/1945	12/16/1999	54	M
552	Jenson	Tory	1204	OD	5/29/1961	1/13/2000	39	F
579	Soper	Robert	1235	OS	3/20/1978	2/17/2000	22	M
257	Aaron	Linda	1236	OS	5/2/1949	8/26/1999	50	F
479	Vang	Yer	1284	OD	6/12/1963	3/16/2000	37	M
578	Ettinger	Jean	1288	OS	1/13/1945	3/16/2000	55	F
341	Chung	Suk Ling	1457	OD	9/9/1958	7/7/2000	42	F
650	Yeo	Jacqueline	1499	OD	4/7/1962	7/13/2000	38	F
650	Yeo	Jacqueline	1500	OS	4/7/1962	7/13/2000	38	F
648	Bagnoli	Al	1529	OS	1/20/1953	8/11/2000	48	M
651	Onofrio	Helen	1544	OD	11/12/1955	8/25/2000	45	F
697	Forstater	Eleanor	1599	OD	12/27/1968	10/27/2000	32	F
697	Forstater	Eleanor	1600	OS	12/27/1968	10/27/2000	32	F
744	Angstadt	Patricia	1714	OD	4/24/1947	1/26/2001	54	F
761	Koenig	Joerg	1760	OD	6/10/1968	2/16/2001	33	M
761	Koenig	Joerg	1761	OS	6/10/1968	2/16/2001	33	M
826	Hartshorne	Joanne	1949	OS	11/3/1948	5/18/2001	53	F
828	Ryan	Cynthia	2007	OD	7/12/1948	5/31/2001	53	F
880	Morgan	Dominic	2182	OD	8/8/1960	4/30/1998	38	M
880	Morgan	Dominic	2183	OS	8/8/1960	4/23/1998	38	M

Case Summaries for Eyes that Lost 2 or More Lines of BCVA

(T-P) 218: T-P is a 44 year old female who underwent uneventful unilateral LASIK surgery on the left eye with the Nevyas Excimer Laser on 3/19/1998. Preoperatively, the manifest refraction was –9.75 x-0.75 x 100; UCVA was 20/1000; and, BSCVA was 20/20. An intentional undercorrection for monovision was performed in this eye with a target residual of –1.75 D MRSE. The patient's postoperative course was unremarkable except for the removal of a chalazion at 3 months postoperatively. BSCVA was reported to be 20/40 at this visit and improved to 20/25 at the 6-month visit, fluctuated to 20/30 (a 2 line loss in BSCVA) at 9 months post-LASIK, and remained at 20/25 for all subsequent visits. At the 24-month end of study visit, BSCVA was 20/25 and the patient offered no complaints.

(M-H) 238: M-H is a 29 year old female who underwent uneventful unilateral LASIK surgery on the left eye with the Nevyas Excimer Laser on 3/4/1999. Preoperatively, the manifest refraction was –9.00 x –1.25 x 15; UCVA was 20/1000; and, BSCVA was 20/20. An intentional undercorrection was performed in this highly myopic eye with a target residual of –0.50 D MRSE. At 6 months postoperatively, the eye had a manifest refraction of –2.00 x –0.25 x 45; UCVA 20/60; and, a BSCVA of 20/30, which was a 2 line decrease from the preoperative BSCVA of 20/20. The eye was retreated 1 week later with the Nevyas Excimer Laser to improve the refractive outcome. At the last reported visit, 12 months post-retreatment, the eye had a manifest refraction of 0.25 x 0.00 x 0; UCVA of 20/25; BSCVA of 20/20, and the patient offered no complaints..

(J-T) 261: J-T is a 4 year old male who underwent unilateral LASIK surgery on the right eye with the Nevyas Excimer Laser on 9/11/1997. The LASIK surgery was unremarkable; surgery was performed using the "old" centration technique. Preoperatively, the eye had a manifest refraction of –7.75 x –1.50 x 7; UCVA was 20/100, and BSCVA was 20/20. Target postoperative refraction was plano. The eye's BSCVA has fluctuated between 20/25 and 20/30 since the 6 month postoperative visit. At the 24-month end of study visit, the eye had a manifest refraction of –0.50 x-0.75 x 75 with a UCVA of 20/70 and BSCVA of 20/30. The patient was seen again at ~4 years post-LASIK and the treated eye showed good refractive stability with a manifest refraction of –0.75 x –0.75 x 77, UCVA of 20/50, and BSCVA of 20/30. The patient is pleased with the result and offers no complaints.

(R-B) 275: R-B is a 48 year old male who underwent LASIK surgery on the left eye on 10/9/1997 with the Nevyas Excimer Laser. The eye was intentionally undercorrected with a target of –1.25 D MRSE. Surgery was performed using the "old" centration technique. Preoperatively, the eye had a manifest refraction of -7.75 x –2,75 x170, UCVA of 20/1000 and BSCVA of 20/20. Postoperatively, the eye was noted to overcorrected. At 6 months postoperatively, the eye had a reported manifest refraction of 6.00 x –1.25 x 120, UCVA of 20/200, and BSCVA of 20/30. At 10 months postoperatively, the eye was retreated using a commercially available laser. At 6 months

post-retreatment, the eye had a manifest refraction of 0.00 x-0.75 x 60 with a UCVA of 20/25 and BSCVA of 20/20.

(K-W) 277/278: K-W is a 40 year old male who underwent LASIK surgery on the left eye on10/7/97 and on the right eye on 10/9/97 with the Nevyas Excimer Laser. Preoperatively, the manifest refraction in the left eye was –13.00 x –0.50 x 135 and –11.25 x-1.00x 10 in the right eye. Both eyes had a preoperative UCVA of 20/2000 and BSCVA of 20/20. The target postoperative refraction was –1.50 MRSE in the left eye and plano in the right eye. At 6 months postoperatively, the left eye was undercorrected with a manifest refraction of –1.50 x –1.50 x140 with an UCVA of 20/100 and a BSCVA of 20/30 and the right eye was overcorrectedwith a manifest refraction of 1.25 x –2.00 x 110 with UCVA BSCVA both reported to be 20/40. An astigmatic keratotomy procedure was planned to treat the residual astigmatism in these eyes.
\RESULTS of AK?

(J-W) 325: J-W is a 49 year old male who underwent unilateral LASIK surgery on the right eye with the Nevyas Excimer Laser on 1/12/1998. The eye had a preoperative manifest refraction of –10.25 x-1.25 x 180, UCVA of 20/1000 and BSCVA of 20/20. The right eye was intentionally undercorrected with a target postoperative refraction of –1.00 MRSE, and was treated using the "old" centration technique. At 1month postoperatively, the patient complained of ghost images and a decentration was observed. The decentration was still noted to be present at 3 months post-LASIK. At 6 months postoperatively, patient was unhappy with his distance vision and glasses were prescribed. The manifest refraction was 0.25 x –0.75 x 95 with UCVA and BSCVA both measured to be 20/30. An AK procedure was performed at approximately 8 months post-LASIK to reduce the residual cylinder. At the last reported visit, 6 months after the AK procedure, the eye had a manifest refraction of –1.50 x –1.24 x 90 with a UCVA of 20/40 and BSCVA of 20/20 and the patient had no complaints.

(S-E) 347: S-E is a 36 year old female who underwent unilateral LASIK surgery on the right eye with the Nevyas Excimer Laser on 12/4/1997. Preoperative manifest refraction was-11.25 x-3.00 x 9 with a UCVAof 20/1000 and BSCVA of 20/30. The eye was intentionally undercorrected with a postoperative target refraction of –1.50 D MRSE; and, surgery was performed using the "old" centration technique. At 6 months postoperatively, the eye was slightly overcorrected with a manifest refraction of 1.25 x –1.00 x 10, UCVA of 20/40 and BSCVA of 20/30. The patient complained of decreased near and distance vision in dim light. At 18 months postoperatively, glasses were prescribed for night time driving. At approximately 36 months post-LASIK, a retreatment procedure was performed to improve the refractive outcome. Preoperative refraction at the time of retreatment was –2.50 x-3.50 x 135. At the last reported visit, 6 months after the retreatment, the eye had a manifest refraction of 2.25 x –1.25x 45 with an UCVA of 20/30 and a BSCVA of 20/25.

Check the +/- signs on these refractions.

Herb Nevyas

From: Stephen Barrett, M.D. [sbinfo@quackwatch.org]
Sent: Wednesday, July 30, 2003 8:07 AM
To: Herb Nevyas:
Subject: Links to lasiksucks4u site

You can find the links to lasiksucks4u.com by using this URL http://www.google.com/search?as_lq=www.lasiksucks4u.com&btnG=Search
--
- - - - - - - - - - - - - - - - -

Stephen Barrett, M.D.
Board Chairman, Quackwatch, Inc.
NCAHF Vice President and Director of Internet Operations P.O. Box 1747, Allentown, PA 18105
Telephone: (610) 437-1795

http://www.quackwatch.org (health fraud and quackery) http://www.chirobase.org (guide to chiropractic) http://www.dentalwatch.org (guide to dental care) http://www.homeowatch.org (guide to homeopathy) http://www.ihealthpilot.org (under construction) http://www.mlmwatch.org (multi-level marketing) http://www.naturowatch.org (naturopathy) -- under construction http://www.nutriwatch.org (nutrition facts and fallacies) http://www.ncahf.org (National Council Against Health Fraud) http://www.chsourcebook.com (consumer health sourcebook)

Editor, Consumer Health Digest http://www.ncahf.org/digest/chd.html
Publisher, Chiropractic News Digest
http://www.quackwatch.org/00AboutQuackwatch/chd.html
Donations of $1 to $50 to help support Quackwatch can be made through
http://s1.amazon.com/exec/varzea/pay/T1X6GUTTCLU3T4

Herb Nevyas

From: Stephen Barrett, M.D. [sbinfo@quackwatch.org]
Sent: Wednesday, July 30, 2003 6:52 AM
To: Herb Nevyas;
Subject: Fwd: Re: lasik surgery

At 9:57 PM -0400 7/29/03, Stephen Barrett, M.D. wrote:
>I just looked at your site again and am curious about two things:
>
>1. When did you put the information on the site?
>2. I would be interested in receiving copies of additional information
>that people send you.
>
>Thanks for calling this to my attention.

======

Mr. Morgan replied:

>X-Original-To: sbinfo@enter.net
>Delivered-To: sbinfo@enter.net
>Date: Tue, 29 Jul 2003 19:55:45 -0700 (PDT)
>From: DOM MORGAN <djm0860@yahoo.com>
>Subject: Re: lasik surgery
>To: "Stephen Barrett, M.D." <sbinfo@quackwatch.org>
>
>dr barrett,
>
>after litigation i started updating my site with names, etc..
>everything has been there, just not posted, due to confidentialy during
>litigation. i did not intentionally want to post this information yet,
>i was waiting until i had 'everything' i wanted to post.
> i am far from done. there is quite a bit more to do.
>
>i beg to differ as far as their practices in that they should have
>never considered me in the first place.
>also their tactics they used, what they told me, and more importantly
>the other persons that were damaged.
>i'm not a vindictive person, but they ruined my life...
>
>what information are you requesting from me pertaining to others? i
>have been in contact with several of nevyas' other patients who were
>damaged, but they are in litigation now.
>
>a question for you...do you know these people personally? i've had
>over 2 years dealing with these people.
>
>dom

--

Stephen Barrett, M.D.
Board Chairman, Quackwatch, Inc.
NCAHF Vice President and Director of Internet Operations P.O. Box 1747, Allentown, PA 18105
Telephone: (610) 437-1795

-- under construction http://www.nutriwatch.org (nutrition facts and fallacies) http://www.ncahf.org (National Council Against Health Fraud) http://www.chsourcebook.com (consumer health sourcebook)

Editor, Consumer Health Digest http://www.ncahf.org/digest/chd.html
Publisher, Chiropractic News Digest
http://www.quackwatch.org/00AboutQuackwatch/chd.html
Donations of $1 to $50 to help support Quackwatch can be made through
http://s1.amazon.com/exec/varzea/pay/T1X6GUTTCLU3T4

Herb Nevyas

From: Stephen Barrett, M.D. [sbinfo@quackwatch.org]
Sent: Tuesday, July 29, 2003 9:54 PM
To: Herb Nevyas:
Subject: Yahoo Involvement

It looks like Yahoo is in the Web hosting business:
http://webhosting.yahoo.com/ps/wh/prod/

Here are Yahoo's "Terms of Service"
http://docs.yahoo.com/info/terms/

Included is this paragraph:
You agree to not use the Service to:
a. upload, post, email, transmit or otherwise make available any Content that is unlawful, harmful, threatening, abusive, harassing, tortious, defamatory, vulgar, obscene, libelous, invasive of another's privacy, hateful, or racially, ethnically or otherwise objectionable;

You should send a complaint by email to abuse@yahoo.com

Also send one to one of their top lawyers jsobel@yahoo-inc.com

The letters should state that the site is violating their terms of service.
The first round should simply provide the facts and should not threaten.
--

Stephen Barrett, M.D.
Board Chairman, Quackwatch, Inc.
NCAHF Vice President and Director of Internet Operations P.O. Box 1747, Allentown, PA 18105
Telephone: (610) 437-1795

http://www.quackwatch.org (health fraud and quackery) http://www.chirobase.org (guide to chiropractic) http://www.dentalwatch.org (guide to dental care) http://www.homeowatch.org (guide to homeopathy) http://www.ihealthpilot.org (under construction) http://www.mlmwatch.org (multi-level marketing) http://www.naturowatch.org (naturopathy) -- under construction http://www.nutriwatch.org (nutrition facts and fallacies) http://www.ncahf.org (National Council Against Health Fraud) http://www.chsourcebook.com (consumer health sourcebook)

Editor, Consumer Health Digest http://www.ncahf.org/digest/chd.html
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http://www.quackwatch.org/00AboutQuackwatch/chd.html
Donations of $1 to $50 to help support Quackwatch can be made through
http://s1.amazon.com/exec/varzea/pay/T1X6GUTTCLU3T4

Herb Nevyas

From: Stephen Barrett, M.D. [sbinfo@quackwatch.org]
Sent: Tuesday, July 29, 2003 9:52 PM
To: Herb Nevyas:
Subject: Fwd: lasik surgery

```
>Return-Path: <sbinfo@ComCAT.COM>
>X-Original-To: sbinfo@enter.net
>Delivered-To: sbinfo@enter.net
>Received: from localhost (localhost [127.0.0.1])
>      by mmail.enter.net (Postfix) with ESMTP id 28A63D5613
>      for <sbinfo@enter.net>; Mon, 28 Jul 2003 22:36:51 -0400 (EDT)
>Received: from mmail.enter.net ([127.0.0.1])
>  by localhost (rmail2.enter.net [127.0.0.1:10024]) (amavisd-new) with
>ESMTP
>  id 61383-238 for <sbinfo@enter.net>; Mon, 28 Jul 2003 22:36:51 -0400
>(EDT)
>Received: from smu0161.ComCAT.COM (smu0161.Comcation.Net [216.3.71.212])
>      by mmail.enter.net (Postfix) with ESMTP id A87BBD560B
>      for <sbinfo@enter.net>; Mon, 28 Jul 2003 22:36:50 -0400 (EDT)
>Received: from smu0161.ComCAT.COM (localhost [127.0.0.1])
>      by smu0161.ComCAT.COM (8.12.9/mh-s/20030519) with ESMTP id
>h6T2a2t0020154
>      for <sbinfo@enter.net>; Mon, 28 Jul 2003 22:36:02 -0400 (EDT)
>Received: (from sbinfo@localhost)
>      by smu0161.ComCAT.COM (8.12.9/Submit) id h6T2a1F9020116
>      for sbinfo@enter.net; Mon, 28 Jul 2003 22:36:01 -0400 (EDT)
>Received: from web10502.mail.yahoo.com (web10502.mail.yahoo.com
>[216.136.130.152])
>      by smu0161.ComCAT.COM (8.12.9/mh-s/20030519) with SMTP id
>h6T2Zmt0019998
>      for <victims@quackwatch.com>; Mon, 28 Jul 2003 22:35:48 -0400 (EDT)
>Message-ID: <20030729023547.90133.qmail@web10502.mail.yahoo.com>
>Received: from [68.60.254.120] by web10502.mail.yahoo.com via HTTP;
>Mon, 28 Jul 2003 19:35:47 PDT
>Date: Mon, 28 Jul 2003 19:35:47 -0700 (PDT)
>From: DOM MORGAN <djm0860@yahoo.com>
>Subject: lasik surgery
>To: victims@quackwatch.com
>
>is not all it's hyped up to be for patients who are not candidates.  i
>was told numerous times before having had lasik that i was a good
>candidate from a supposedly reputable laser center (nevyas eye
>associates - bala cynwyd, pa...whom you have articles
>written by).  my complete story is at:
>       www.lasiksucks4u.com
>these people ruined my eyes, my vision, and my life!!
>there are a growing number of people damaged by this procedure, who
>were told they were good candidates.
>when does it stop?
>
>dom
```

Herb Nevyas

From: Stephen Barrett, M.D. [sbinfo@quackwatch.org]
Sent: Tuesday, July 29, 2003 9:11 PM
To: Herb Nevyas:
Subject: Whois Information

"lasiksucks4u.com" is registered with whois.melbourneit.com:

Domain Name..... lasiksucks4u.com
Creation Date..... 2002-02-08
Registration Date.... 2002-02-08
Expiry Date..... 2004-02-08
Organisation Name.... Dominic J Morgan
Organisation Address. PO BOX 168
Organisation Address.
Organisation Address. Marlton
Organisation Address. 08053
Organisation Address. NJ
Organisation Address. UNITED STATES

Admin Name..... Dominic J Morgan
Admin Address..... PO BOX 168
Admin Address.....
Admin Address..... Marlton
Admin Address..... 08053
Admin Address..... NJ
Admin Address..... UNITED STATES
Admin Email..... lasiksucks4u@lasiksucks4u.com Admin Phone..... 856-979-5123
Admin Fax.....

Tech Name..... YahooDomains Techcontact Tech Address..... 701 First Ave.
Tech Address.....
Tech Address..... Sunnyvale
Tech Address..... 94089
Tech Address..... CA
Tech Address..... UNITED STATES
Tech Email..... domain.tech@YAHOO-INC.COM Tech Phone..... +1.6198813096 Tech
Fax.....
Name Server..... ns8.san.yahoo.com
Name Server..... ns9.san.yahoo.com

Whois Server Version 1.3

Domain names in the .com and .net domains can now be registered with many different competing registrars. Go to http://www.internic.net for detailed information.

Domain Name: LASIKSUCKS4U.COM
Registrar: MELBOURNE IT, LTD. D/B/A INTERNET NAMES WORLDWIDE Whois Server: whois.melbourneit.com Referral URL: http://www.melbourneit.com Name Server: NS8.SAN.YAHOO.COM Name Server: NS9.SAN.YAHOO.COM
Status: ACTIVE
Updated Date: 27-jan-2003
Creation Date: 08-feb-2002
Expiration Date: 08-feb-2004

>>> Last update of whois database: Tue, 29 Jul 2003 18:02:09 EDT

Pneumatic Trabeculoplasty (PNT) for Glaucoma

Stephen Barrett, M.D.

Glaucoma is a group of disorders in which increased pressure within the eyeball (intraocular pressure) can damage the eye and cause impaired vision, ranging from slight impairment to complete blindness. The pressure is caused by an imbalance between production and drainage of the intraocular fluid (aqueous humor). Most cases of glaucoma can be controlled with eyedrops [1]. Oral medication and/or surgery may be used when control cannot be achieved with the drops.

In 1997, the Arizona Glaucoma Institute (AGI), of Scottsdale, Arizona, began offering a "new treatment" for open-angle and pigmentary glaucoma using a patented vacuum-ring device. Devices of this type are FDA-approved for stabilizing the eye during refractive (lens) surgery, but they are not approved for use in treating glaucoma. The institute's parent company, Coronado Industries , marketed the device through another subsidiary called Ophthalmic International. Patent information for the device states:

The open angle glaucoma treatment apparatus is a vacuum source and a vacuum applicator coupled by a hose. The vacuum applicator is an eye ring or an eye cup that is placed on the frontal surface of an eye. Suction (negative pressure) in the range of 10 to 30 mm. Hg. is applied by the vacuum source, which will fixure the ring or cup to the eye, or alternatively pressure is applied for 15 to 120 seconds. A second treatment is recommended later. It could be within twelve hours, on the following day, or within the next couple of days [2].

An AGI brochure stated that a 2-minute treatment with the device "lowers intra-ocular pressure in most cases." [3] Another institute document states that during the previous four years, "a good number" of patients have been taken off of their medication completely and that "a number of patients" have remained on medication but required reduced dosage [4]. PNT costs about $200 per treatment. In September 1997, the institute offered free glaucoma screenings in connection with its"grand opening." [5]

In early 1998, an Arizona investment firm seeking investors for Coronado Industries issued a private offering summary which noted that the AGI's medical director, ophthalmologist Leo D. Bores, M.D., had originated the radial keratotomy procedure [6]. The solicitation, intended "for broker-dealer internal use only," projects after-tax earnings of $12 million in 1998, $46 million in 1999, and $99 million in the year 2000. The solicitation also states that the proceeds will be used to open additional Glaucoma Treatment Centers and that Coronado Industries believes that "insurance companies will . . . quickly approve payment for the new device and procedure since it is projected to reduce the cost of long-term care costs associated with alternative treatments." [6] However, the company's Form SB-2 Registration Statement filed with the Securities and Exchange Commission on 8/24/98, noted receipts of $179,767 and an overall loss of $648,702 for the first half of 1998 [7]. The report also stated:

In March 1998, the company's Scottsdale treatment center began receiving Medicare payments for . . . the PNT procedure. There is no assurance that these payments will continue . . . and as to when, if ever, the Company will receive payments at . . . additional centers from third-party payors [7].

Safety and Effectiveness Questioned

The fluid within the eyeball normally drains through the trabecular meshwork, a thin net-like band that lies between between the cornea (the clear window of the eye) and the sclera (the white portion of the eye). Glaucoma usually occurs because the mesh becomes clogged or is unable to allow sufficent drainage. When this happens, since fluid production continues, intraocular pressure builds up.

Normal eye pressures range from 8 to 20 millimeters of mercury (mm Hg). In high-pressure glaucoma, the levels range from 21 to 40. In rare cases, new patients present with higher levels. The higher the pressure, the more likely that optic nerve damage will occur. PNT is postulated to reduce pressure within the eye by squeezing fluid out through the trabecular meshwork. However, fluid production continues, so unless the procedure can improve the drainage system itself, any pressure reduction would be short-lived.

PNT temporarily squeezes the front of the eyeball and raises the intraocular pressure to 65 and perhaps even higher. In someone with an already damaged optic nerve, this could be serious. The accepted treatment for glaucoma is to lower the pressure with medication or surgery. Experiments in monkeys have demonstrated that sudden pressure elevations can compromise the blood supply to the optic nerve and accelerate nerve cell death in already weakened cells [8,9], and human experiments have found that acute pressure increases can increase cupping of the optic nerve [10,11]. Two cases have been reported of patients who lost part of their vision following LASIK operations during which their intraocular pressure was temporarily raised when a suction ring was applied to their eyeball [12,13]. For these reasons, until proven safe, PNT should be viewed with caution. Damage from high intraocular pressure may not be immediately apparent. As a result, patients having PNT may not be able to tell whether they are being harmed until it is too late to reverse the damage. Proof of safety and effectiveness would require long-term studies showing not only that intraocular pressure is lowered, but also that the patients' visual fields have not been adversely affected.

To date, no peer-reviewed journal has published a study demonstrating that PNT actually works or is safe. Preliminary reports by Dr. Bores, a Mexican ophthalmologist (Guillermo Avalos, M.D.), and ophthalmologist John LiVecchi, M.D. (described in the brochure as a director and major shareholder of Coronado Industries) have claimed positive results. A report on Coronado Industries' Web site in November 1998 stated that at least 250 patients had been treated for up to 3.5 years, with "maintenance therapy as frequently as every 2-3 months to yearly." These reports claimed various levels of effectiveness, with the drop in pressure being greatest in people whose problem was least severe when they sought treatment. However, a study conducted at the Duke University School of Medicine found that PNT did not lower intraocular pressure among 20 patients with uncontrolled glaucoma. Each patient had one eye treated while the other served as a control. Measurements at one hour, two hours, one day, one week, one month, and three months later found no reduction of intraocular pressure or improvement in the drainage of fluid from within the eye [14]. The reports from Drs. Bores, Avelos, and LaVecchi did not contain such comparative data or compare their patients to a control group of similar patients who did not undergo PNT.

FDA Objections

Documents obtained with a Freedom of Information Act request indicate that in February 1998, the FDA issued a warning letter to Ophthalmic International president G. Richard Smith. The letter stated:

During an inspection of your firm conducted between November 25 and December 11, 1997,

our investigators determined that your firm distributed two vacuum fixation devices with suction rings to the Arizona Glaucoma Institute. . . for use in treating patients with glaucoma using a pneumatic trabeculoplasty (PNT) procedure. These products are devices as defined by . . . the Federal Food, Drug, and Cosmetic Act.
Your vacuum fixation devices are adulterated . . . in that they are Class III devices. . . and do not have approved applications for investigational device exemption (IDE). . . . Your . . . devices are also misbranded . . . in that a notice or other information respecting the devices was not provided to the FDA as required [15].
The letter indicated that because the device is not approved for the treatment of glaucoma, the FDA regards it as a new device for which FDA approval is required and that:
The sponsors of investigations, investigators, or any persons acting for or on behalf of a sponsor or an investigator may not promote or test market an investigational device or represent that it is safe or effective for the purpose for which it is being investigated.
Smith replied that the vacuum fixation device does have an IDE and should not be considered a Class III device, that an Institutional Review Board (IRB) had determined that the device did not pose an unreasonable risk to patients, and that his company plans to submit an application to broaden the way the device is used [16]. However, an FDA official responded that the device had not been formally classified, that new devices are automatically placed in Class III, and that the agency disagreed with the IRB's conclusion [17]. In August 1998, the company submitted an IDE application [7], which the FDA rejected.

Disciplinary Action

In March 1999, Dr. Bores announced that he had retired from clinical practice but would continue to direct research at the American Eye Institute , with which AGI had merged [18]. In December 1999, after additional communication with the FDA, Ophthalmic International was given permission to conduct a small "feasibility study." [19] Federal regulations state that during clinical studies, no investigator or sponsor can commercially distribute an unapproved device, charge subjects more than the amount needed to cover costs, or represent that the device is safe or effective for its intended purpose. According to information from the Arizona Medical Board, Bores did all of these things, lacked FDA approval to conduct any PNT studies, and improperly collected Medicare payments for patients treated between December 1997 and February 1999. In April 2003, the board reprimanded Bores and placed him on two years' probation under which he is barred from conducting studies that do not meet FDA criteria and must reimburse Medicare for $15,539.81 that he had been paid for the 1997-1999 treatments [19].

The Bottom Line

Pneumatic trabeculoplasty has not been proven safe or effective for treating glaucoma; and Coronado Industries' vacuum fixation device lacks FDA approval for such use. It remains to be seen whether additional research will demonstrate benefit.

For Additional Information

Additional information about glaucoma can be obtained from:

- American Academy of Ophthalmology
- Glaucoma Foundation : (800) 452-8266. Has a 20-page brochure online.
- Glaucoma Research Foundation : (800) 826-6693.
- National Eye Institute
- State ophthalmic or optometric boards

- Don't Waste Money on Overpriced Eyedrops

References

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4. "Dear Glaucoma Patient." Letter from Arizona Glaucoma Institute. Undated, acquired in 1997.
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19. Consent agreement and order for letter of reprimand and probation. In the matter of Leo Bores, M.D. Arizona Medical Board Case # MD-97-0948, April 4, 2003.

Quackwatch Home Page

This article was updatd on May 31, 2003.

Title 21—Food and Drugs

Chapter 1

FOOD AND DRUG ADMINISTRATION

DEPARTMENT OF HEALTH AND HUMAN SERVICES

PART 56 — Institutional Review Boards

Subpart A — General Provisions

§56.101 Scope.

(a) This part contains the general standards for the composition, operation, and responsibility of an Institutional Review Board (IRB) that reviews clinical investigations regulated by the Food and Drug Administration under sections 505(i), 507(d), and 520(g) of the act, as well as clinical investigations that support applications for research or marketing permits for products regulated by the Food and Drug Administration, including food and color additives, drugs for human use, medical devices for human use, biological products for human use, and electronic products. Compliance with this part is intended to protect the rights and welfare of human subjects involved in such investigations.

(b) References in this part to regulatory sections of the Code of Federal Regulations are to Chapter I of Title 21, unless otherwise noted.

§56.102 Definitions.

As used in this part:

(a) "Act" means the Federal Food, Drug, and Cosmetic Act, as amended (secs. 201-902, 52 Stat. 1040 et seq., as amended (21 U.S.C. 321-392)).

(b) "Application for research or marketing permit" includes:

(1) A color additive petition, described in Part 71.

(2) Data and information regarding a substance submitted as part of the procedures for establishing that a substance is generally recognized as safe for a use which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food, described in §170.35.

(3) A food additive petition, described in Part 171.

(4) Data and information regarding a food additive submitted as part of the procedures regarding food additives permitted to be used on an interim basis pending additional study, described in §180.1.

(5) Data and information regarding a substance submitted as part of the procedures for establishing a tolerance for unavoidable contaminants in food and food-packaging materials, described in section 406 of the act.

(6) An investigational new drug application, described in Part 312 of this chapter.

(7) A new drug application, described in Part 314.

(8) Data and information regarding the bioavailability or bioequivalence of drugs for human use submitted as part of the procedures for issuing, amending, or repealing a bioequivalence requirement, described in Part 320.

(9) Data and information regarding an over-the-counter drug for human use submitted as part of the procedures for classifying such drugs as generally recognized as safe and effective and not misbranded, described in Part 330.

(10) Data and information regarding an antibiotic drug submitted as part of the procedures for issuing, amending, or repealing regulations for such drugs, described in §314.300 of this chapter.

(11) An application for a biological product license, described in Part 601.

(12) Data and information regarding a biological product submitted as part of the procedures for determining that licensed biological products are safe and effective and not misbranded, as described in Part 601.

(13) An "Application for an Investigational Device Exemption," described in Parts 812 and 813.

(14) Data and information regarding a medical device for human use submitted as part of the procedures for classifying such devices, described in Part 860.

(15) Data and information regarding a medical device for human use submitted as part of the procedures for establishing, amending, or repealing a standard for such device, described in Part 861.

(16) An application for premarket approval of a medical device for human use, described in section 515 of the act.

(17) A product development protocol for a medical device for human use, described in section 515 of the act.

(18) Data and information regarding an electronic product submitted as part of the procedures for establishing, amending, or repealing a standard for such products, described in section 358 of the Public Health Service Act.

(19) Data and information regarding an electronic product submitted as part of the procedures for obtaining a variance from any electronic product performance standard, as described in §1010.4.

(20) Data and information regarding an electronic product submitted as part of the procedures for granting, amending, or extending an exemption from a radiation safety performance standard, as described in §1010.5.

(21) Data and information regarding an electronic product submitted as part of the procedures for obtaining an exemption from notification of a radiation safety defect or failure of compliance with a radiation safety performance standard, described in Subpart D of Part 1003.

(c) "Clinical investigation" means any experiment that involves a test article and one or more human subjects, and that either must meet the requirements for prior submission to the Food and Drug Administration under section 505(i), 507(d), or 520(g) of the act, or need not meet the requirements for prior submission to the Food and Drug Administration under these sections of the act, but the results

(W-S) 407: W-S is a 32 year old male who underwent unilateral LASIK surgery on the left eye with the Nevyas Excimer Laser on 4/9/1998. The surgery was unremarkable except that pannus was noted as an ablation complication. Target postoperative manifest refraction was –1.50 MRSE. At 6 months postoperatively, the eye had a manifest refraction of 0.50 x –0.25 x 90, with an UCVA of 20/40 and BSCVA of 20/30. At 12 months postoperatively, the refraction improved to 0.00 x –0.75 x 165 with the UCVA and BSCVA both reported as 20/30.

(C-H) 612: C-H is a 41 year old female who underwent LASIK surgery on the left eye with the Nevyas Excimer Laser on 9/10/1998. Preoperatively, the eye had a manifest refraction of –8.00 x-1.50 x164 with an UCVA of 20/1000 and BSCVA of 20/20. The eye was intentionally undercorrected with a target postoperative refraction of –1.25 D MRSE. At 6 months postoperatively, the manifest refraction was –1.00 x-0.50 x 90 with an UCVA of 20/70 and BSCVA of 20/40. BSCVA measured at an unscheduled visit performed one month later, and at all subsequent scheduled visits, was 20/20. The transient decrease in BSCVA observed at 6 months was most likely due to technician error.

(L-W) 825/826: L-W is a 40 year old female who underwent bilateral same-day LASIK surgery on the right and left eyes with the Nevyas Excimer Laser on 9/2/1999. Preoperatively, the manifest refraction was –8.75 x –0.50 x 100 in the right eye and –8.75 x-0.75 x 38 in the left eye, with both eyes having an UCVA of 20/1000 and BSCVA of 20/20. A monovision treatment was performed with the left eye intentionally undercorrected to a target postoperative refraction of –1.25 D MRSE and the right eye targeted to plano. At 6 months postoperatively, the right eye was overcorrected with a manifest refraction of 1.75 x –1.25 x 135, with an UCVA of 20/50 and a BSCVA of 20/30. The left eye had attained its targeted undercorrection with a manifest refraction of –1.00 x –0.50 x 15, with a distance UCVA of 20/70 and BSCVA of 20/40. No additional visit information is available for either of these eyes.

(M-N) 928: M-N is a 50 year old male who underwent bilateral same-day LASIK surgery on the right and left eyes with the Nevyas Excimer Laser on 5/7/1999. The intraoperative and postoperative course of the right eye was unremarkable with no change in BSCVA. A superotemporal tear on the corneal flap edge was noted as a keratectomy complication during the surgery on the left eye. Preoperatively, the eye had a manifest refraction of –4.00 x –1.00 x 175, with a UCVA of 20/200, and a BSCVA of 20/20. The eye was intentionally undercorrected for monovision with a target refraction of –1.50D MRSE. At 12 months postoperatively, the left eye had a 2-line loss in BSCVA (BSCVA = 20/30). At the 24 month end of study visit, the left eye had a manifest refraction of –1.00 x-0.50 x 110 with an UCVA of 20/30 and BSCVA of 20/20.

(P-D) 1019: P-D is a 55 year old male who underwent bilateral same-day LASIK surgery on the right and left eyes with the Nevyas Excimer Laser on 8/12/1999. The

intraoperative and postoperative course of the right eye was unremarkable, with no change in BSCVA (BSCVA = 20/20) at all visits. The left eye reported a single 2-line loss in BSCVA at the 12-month visit. Manifest refraction was +0.50x –1.50 x 107 with an UCVA of 20/30. BSCVA was reported as 20/20 at all other visits. The isolated report of BSCVA loss is believed due to technician error or variability in obtaining the BSCVA measurement.

(R-A) 1021/1022: R-A is a 47 year old female who underwent bilateral same-day LASIK surgery on the right and left eyes with the Nevyas Excimer Laser on 8/12/1999. Preoperatively, the manifest refraction was –6.00 x-2.00 x 165 in the right eye and –5.25 x –2.50 x 168 in the left eye. Both eyes had a preoperative UCVA of 20/1000 and BSCVA of 20/15. A monovision treatment was performed with a targeted postoperative refraction of +0.25 D MRSE in the right eye and –1.25 D MRSE in the left eye. Both eyes reported a BSCVA of 20/25 (2 line loss) at 18 months postoperatively. Manifest refraction at this visit was +1.25 x –0.75 x 158 with a UCVA of 20/25 in the right eye and –0.50 x –0.50 x 65 with a UCVA of 20/25 in the left eye. At the 24-month end of study visit, the left eye had a manifest refraction of –0.75 x –0.25 x 150, UCVA of 20/30, and BSCVA of 20/20. The right eye had a LTK procedure performed at ~18 months postoperatively, and at 12 months post-LTK the manifest refraction is 0.00 x-0.75 x 20 with an UCVA of 20/25 and a BSCVA of 20/20.

(J-R) 1037: J-R is a 23 year old male who underwent bilateral same-day LASIK surgery on the right and left eyes with the Nevyas Excimer Laser on 12/20/1999. The intraoperative and postoperative course of the left eye was unremarkable, except for the complaint of redness and dryness and 6 months postoperatively. Preoperatively, the right eye had a manifest refraction of 06.50 x –0.50 x 103, with a UCVA of 20/1000 , and a BSCVA of 20/20 . The eye was intentionally overcorrected with a target refraction of +0.25D MRSE. The right eye had a single report of BSCVA loss at the 24-month end of study visit. The manifest refraction in the right eye of –0.50 x –0.75 x 90 was unchanged from the 12-month visit. UCVA at 24 months was 20/30, compared to 20/25 at 12-months, and BSCVA was 20/30. BSCVA was reported to be 20/20 at all other postoperative visits, including the 12-month visit. The change in BSCVA is believed to be due to technician variability rather than any true change in vision, especially since the manifest refraction has remained stable throughout the postoperative course.

(D-P) 1107/1108: D-P is a 54 year old male who underwent bilateral same-day LASIK surgery on the right and left eyes with the Nevyas Excimer Laser on 9/17/1999. Preoperatively, the manifest refraction was –6.50 x-0.00 x 0 in the right eye and –6.50 x –0.00 x 0 in the left eye. Both eyes had a preoperative UCVA of 20/1000 and BSCVA of 20/20. A monovision treatment was performed with a targeted postoperative refraction of –2.00 D MRSE in the right eye and plano in the left eye. The postoperative course of each eye was unremarkable, except for the notation of two inferior spots of stain on slit lamp examination of the right eye at 1 month postoperatively. Both eyes reported a BSCVA of 20/30 (2 line loss) at 6 and 12 months postoperatively. At 12 months postoperatively, the manifest refraction is –0.75 x 0x 0 for the intentionally

undercorrected right eye (distance UCVA = 20/40) and +0.75 x 0 x 0 (distance UCVA = 20/25). The patient is happy with the current vision and offers no complaints.

(C-W) 1191/1192: C-W is a 54 year old male who underwent bilateral same-day LASIK surgery on the right and left eyes with the Nevyas Excimer Laser on 12/16/1999. Preoperatively, the manifest refraction was –6.75 x-2.50 x 25 in the right eye and –5.50 x –2.25 x 163 in the left eye. Both eyes had a preoperative UCVA of 20/1000 and BSCVA of 20/20. The targeted postoperative refraction was plano for both eyes. The postoperative course was unremarkable except for the complaint of halos and glare in both eyes at 1 to 3 months post-LASIK. BSCVA in the left eye ranged between 20/100 at 6months and 20/40 at 12 months postoperatively, primarily due to a high degree of residual cylinder (range –2.25 to –3.75 D). The right eye had a single report of a 2-line loss in BSCVA at 9 months postoperatively (BSCVA=20/30) with a moderate amount of residual cylinder (range = -1.75 to –2.75 D) reported postoperatively. At 12 months post-LASIK, the manifest refraction was +1.75 x –2.25 x 45 in the right eye (UCVA = 20/30; BSCVA =20/40) and +0.75 x –1.75 x 135 (UCVA = 20/30; BSCVA = 20/20). An AK procedure was performed on each eye to reduce the amount of residual cylinder, followed by a LASIK retreatment procedure in the left eye to improve the refractive error. At 1 month after the AK procedure, the right eye has a manifest refraction of –1.00x –0.75 x 22 (UCVA = 20/70; BSCVA = 20/40). Further improvement in vision is expected as the eye continues to heal from the procedure. The left eye, at 3 months after the last refractive procedure, has a manifest refraction of +0.50 x 0 x 0 (UCVA = 20/25; BSCVA = 20/25.).

(T-J) 1204: T-J is a 39 year old female who underwent bilateral same-day LASIK surgery on the right and left eyes with the Nevyas Excimer Laser on 1/13/2000. The surgical procedure was unremarkable except for the occurrence of a tear superiorly on corneal flap of the right eye, which was noted as a keratectomy complication. Preoperatively, the manifest refraction was –7.50 x –2.25 x 164 in the left eye and –8.25 x –2.00 x 13 in the right eye. Both eyes had a preoperative UCVA of 20/1000 and BSCVA of 20/20. At 3 months postoperatively, the subject complained of starbursts around headlights, ghost images, and problems with distance vision in both eyes. At 6 months postoperatively, interface haze was observed in both eyes and epithelial haze was noted in the left eye only, with each eye reporting a 1-line loss in BSCVA (BSCVA = 20/25). At 18 months postoperatively, a mild superior decentration was observed in the right eye and the patient complained of double vision in this eye. Manifest refraction in the right eye was –0.75 x –1.25 x 49, with an UCVA of 20/50 and BSCVA of 20/30 (2-line loss in BSCVA). At the 24 month end of study visit, the BSCVA returned to 20/25 in the right eye and BSCVA was reported as 20/20 in the left eye.

(R-S) 1235: R-S is a 22 year old male who underwent bilateral same-day LASIK surgery on the right and left eyes with the Nevyas Excimer Laser on 2/17/2000. Preoperatively, the manifest refraction was –3.75 x –2.00 x 25 in the right eye and –4.00 x –2.25 x 160 in the left eye. Target postoperative refraction for both eyes was +0.25 D MRSE. The intraoperative and postoperative course was unremarkable for both eyes. Both eyes were

evaluated at 3 months (BSCVA = 20/20 in both eyes) and then lost to follow-up until the 24 month end of study visit. At 24 months postop, the right eye had a manifest refraction of –1.00 x 0.00 x 0, UCVA of 20/25, and BSCVA of 20/15. The left eye reported a manifest refraction of –0.75 x –1.50 x 120, UCVA of 20/40, and BSCVA of 20/30 (2-line loss of BSCVA). Since this patient missed all visits between the 3 and 24months postoperatively, it is unknown if the loss in BSCVA was progressive or an isolated occurrence.

(L-A) 1236: L-A is a 50 year old female who underwent unilateral LASIK surgery on the left eye with the Nevyas Excimer Laser on 8/26/1999. Preoperatively, the eye had a manifest refraction of –1.25 x –2.50 x 178, with a UCVA of 20/200 and BSCVA of 20/15. Target postoperative refraction was +0.25D MRSE. The intraoperative and postoperative course was unremarkable for this eye, except for the complaint of fluctuating vision at the 6 and 9 month visits. At 6 months postoperatively, the eye had a manifest refraction of 0.00 x 1.75 x 170, UCVA of 20/100, and BSCVA of 20/60 (5-line loss in BSCVA). At 9 months postoperatively, the manifest refraction was 0.50 x –2.50 x 175, UCVA of 20/40, and BSCVA of 20/20. The BSCVA was recorded as 20/20 at the 1 and 3 month visits and for all visits after 9 months. The transient loss in BSCVA at 6 months is related to the fluctuating vision experienced by the patient at the 6 and 9 month visits. The cause for the fluctuating vision is unknown.

(Y-V) 1284: Y-V is a 37 year old male who underwent LASIK surgery on the right with the Nevyas Excimer Laser on 3/16/2000. Preoperatively, the right eye had a manifest refraction of –3.25 x –0.75 x 20, UCVA of 20/400 and BSCVA of 20/15. The target postoperative refraction was plano. The patient was noncompliant with the postoperative visit schedule, missing all visits between 1 week and 12 months post-LASIK and the 18 and 24 month visits. At 12 months postoperatively, the right eye had a manifest refraction of –1.50 x –0.75 x 15, UCVA of 20/80, and a BSCVA of 20/25 (2-line loss in BSCVA).

(J-E) 1288: J-E is a 55 year old female who underwent unremarkable bilateral same-day LASIK surgery on the right and left eyes with the Nevyas Excimer Laser on 3/16/2000. The postoperative course of the right eye was unremarkable, with no change in BSCVA. Preoperatively, the right eye had a manifest refraction of –6.00 x 0.00 0 and the left eye had a manifest refraction of –8.75 x –0.00 x 0. Both eyes had a preoperative UCVA of 20/1000 and a BSCVA of 20/20 . The left eye was intentionally undercorrected with a target refraction of –1.75D MRSE. At 6 months postoperatively, the manifest refraction in the left eye was –3.50 x 0 x 0. The UCVA was reported to be 20/25 and the BSCVA to be 20/400. Since the UCVA was ranged between 20/50 and 20/400 and the BSCVA ranged between 20/20 and 20/25 at all prior and all subsequent visits, this isolated loss in BSCVA appears to be a data entry error on the source documents and that the UCVA and BSCVA readings were reversed when the measurements were recorded.

(S-C) **1457**: S-C is a 42 year old female who underwent unremarkable bilateral same-day LASIK surgery on the right and left eyes with the Nevyas Excimer Laser on 7/7/2000. Postoperative course of the left eye was unremarkable, with no loss in BSCVA at the last recorded visit. Preoperatively, the right eye had a manifest refraction of –8.50 x 1.25 x 8 and the left eye had a manifest refraction of –8.25 x –1.00 x 165. Both eyes had a preoperative UCVA of 20/1000 and a BSCVA of 20/20. The left eye was intentionally undercorrected with a target refraction of –1.75D MRSE and target refraction in the right eye was +0.25D MRSE. At 6 months postoperatively, the right eye had a manifest refraction of –2.25 x –0.25 x 157, UCVA of 20/200, and a BSCVA of 20/40 (3-line loss in BSCVA). No other information is available on the outcome of this eye.

(J-Y) **1499/1500**: J-Y is a 38 year old female who underwent bilateral same-day LASIK surgery on the right and left eyes with the Nevyas Excimer Laser on 7/13/2000. Preoperatively, the manifest refraction was –10.00 x-0.75 x 105 in the right eye and –7.25 x –0.50 x 60 in the left eye. Both eyes had a preoperative UCVA of 20/1000 and BSCVA of 20/20. A monovision treatment was performed with a targeted postoperative refraction of –1.25 D MRSE in the right eye and +0.25 D MRSE in the left eye. At 12 months postoperatively, the right eye had a manifest refraction of –4.00 x –0.50 x 145, UCVA of 20/60, and BSCVA of 20/30 (2-line loss in BSCVA). A LASIK retreatment procedure was performed and at 6 months post-retreatment, the right eye had a manifest refraction of –1.00 x –0.25 x 80, UCVA of 20/50 and BSCVA of 20/25. The left eye had a single report of a 2-line loss in BSCVA (BSCVA – 20/30) at 12 month postoperatively; BSCVA was 20/20 at the 1 and 3-month visits and the patient missed the 6-month visit. At the 18-month postoperative visit, the manifest refraction in the left eye was –1.50 x –0.25 x 105, UCVA of 20/30, and BSCVA of 20/20. No further treatment is planned for either eye at this time and the patient continues to be followed actively in the study.

(A-B) **1529**: A-B is a 48 year old male who underwent unremarkable bilateral same-day LASIK surgery on the right and left eye with the Nevyas Excimer Laser on 8/11/2000. Preoperatively, the right eye had a manifest refraction of –7.25 x -1.00 x 110 and the right eye had a manifest refraction of –8.25 x –1.00 x 90. Preoperative UCVA was 20/1000 in both eyes and the BSCVA was 20/25 in the right eye and 20/20 in the left eye. A monovision treatment was performed with the left eye being intentionally undercorrected to a target of –1.25 D MRSE. The postoperative course was unremarkable in both eyes, except for the complaint at 3 months of the distance vision being blurry in both eyes. At 6 months postoperatively, the left eye reported a 2-line loss in BSCVA with a manifest refraction of –2.25 x –0.50 x 90, UCVA of 20/70, and BSCVA of 20/30. A LASIK retreatment procedure was performed on the left eye to reverse the monovision treatment; target post-retreatment refraction was +0.25 D. At 12 months post-retreatment, the left eye has a manifest refraction of 0.75 x –0.25 x 110, UCVA of 20/25, and BSCVA of 20/20.

(H-O) **1544**: H-O is a 45 year old female who underwent unremarkable bilateral same-day LASIK surgery on the right eye with the Nevyas Excimer Laser on 8/25/2000. Preoperatively, the right eye had a manifest refraction of –6.50 x –0.50 x 45 and the left

eye had a manifest refraction of –7.25 x –0.50 x 75. Preoperative UCVA was 20/1000 and BSCVA was 20/25 in both eyes. A monovision treatment was performed and the right eye was intentionally undercorrected with a target refraction of –1.50D MRSE. Postoperative course was unremarkable for both eyes, except the patient complained of problems with distance vision in both eyes at 6 months postoperatively. At this visit, the right eye had a manifest refraction of –1.00 x –0.25 x 45, UCVA of 20/50, and BSCVA of 20/40 (2-line loss in BSCVA); the left eye had a manifest refraction of –0.25 x –0.50 x 10, with a UCVA of 20/40 and BSCVA of 20/30 (1-line loss in BSCVA). Both eyes underwent LASIK retreatments to reverse the monovision. At 12 month postoperatively, both eyes have regained their preoperative BSCVA of 20/25.

(E-F) **1599/1600**: E-F is a 32 year old female who underwent bilateral same-day LASIK surgery on the right and left eyes with the Nevyas Excimer Laser on 10/27/2000. Preoperatively, the manifest refraction was –12.00 x-0.00 x 0 in the right eye and –10.75 x –0.75 x 45 in the left eye. Both eyes had a preoperative UCVA of 20/1000 and BSCVA of 20/20. The targeted postoperative refraction was +0.25 D MRSE for both eyes. The intraoperative and postoperative courses were unremarkable for both eyes. The right eye reported a BSCVA of 20/30 (2 line loss) at 6 months postoperatively, which improved to 20/25 at 18 months post-LASIK. The left eye reported a single occurrence of a 2-line loss in BSCVA at the 18 month visit (BSCVA = 20/30). Manifest refraction at 18 months post-LASIK is –1.50 x 0.00 x 0 in the right eye and –0.50 x –0.75 x 165 in the left eye. Both eyes remain in follow-up and no treatment is planned at this time.

(P-A) **1714**: P-A is a 54 year old female who underwent bilateral LASIK surgery on the right and left eyes with the Nevyas Excimer Laser on 1/26/2001. Preoperatively, the manifest refraction was 7.75 x-2.00 x 180 in the right eye and –800 x –1.25 x 2 in the left eye. Both eyes had a preoperative UCVA of 20/1000 and BSCVA of 20/20. A monovision treatment was performed with a targeted postoperative refraction of +0.25 D MRSE in the right eye and –2.00 D MRSE in the left eye. The postoperative course for the left eye was unremarkable. At 6 months postoperatively, the right eye had a manifest refraction or +0.50 x –0.75 x 150, with an UCVA and BSCVA both reported to be 20/30 (2 line loss in BSCVA). At the last scheduled visit (12 months postop), the manifest refraction was +0.50 x –0.75 x150 in the right eye and –1.75 x-0.75 x 10 in the intentionally undercorrected left eye. Both eyes had a distance UCVA of 20/70 and distance BSCVA of 20/30 (2 line loss in BSCVA) in the right eye and 20/20 in the left eye.

(J-K) **1760/1761**: J-K is a 33 year old male who underwent bilateral same-day LASIK surgery on the right and left eyes with the Nevyas Excimer Laser on 2/16/2001. Fine vertical movements during fixation were noted intraoperatively with the right eye. Preoperatively, the manifest refraction was –8.50 x-2.75 x 3 in the right eye and –9.00 x –3.00 x 165 in the left eye. Both eyes had a preoperative UCVA of 20/1000 and BSCVA of 20/20. A monovision treatment was performed with a targeted postoperative refraction of –0.75 D MRSE in the right eye and +0.25 D MRSE in the left eye.

Postoperatively, corneal wrinkles were noted in the flap of both the right and left eyes at 1 month and 3 months postoperatively. At 6 months postoperatively, an epithelial defect was noted in the left eye. The manifest refraction was –1.25 x-1.50 x 70 in the left eye with an UCVA of 20/100 and BSCVA of 20/50 (4 line loss in BSCVA). The patient was seen approximately every 6 weeks for the next 6 months, and BSCVA subsequently improved in the left eye to 20/30 at the next (7 month) visit and then fluctuated between 20/25 and 20/20 at each of the subsequent visits. The right eye had a measured BSCVA of 20/30 (2 line loss) at the 6 month visit with a BSCVA of 20/25 or 20/20 reported at each visit thereafter. At 12 months postoperatively, the right eye had a manifest refraction of –0.75 x –2.00 x 160, UCVA of 20/50, and BSCVA of 20/25. The left eye had a manifest refraction of –1.50 x –2.50 x 125, UCVA of 20/70 and BSCVA of 20/25. A retreatment was performed in each eye with a commercially available laser to improve vision. At 1 month postoperatively, the right eye has a manifest refraction of 0.00 x –0.25 x 28, UCVA and BSCVA of 20/25; the left eye has a manifest refraction of –0.50 x –0.75 x 60, UCVA of 20/40 and BSCVA of 20/25.

(J-H) 1949: J-H is a 53 year old female who underwent bilateral same-day LASIK surgery on the right and left eyes with the Nevyas Excimer Laser on 5/18/2001. The right eye was retreated at 3 months postoperatively to improve the refractive outcome and had a 1 line gain in BSCVA at 1 month post-retreatment. Preoperatively, the left eye had a manifest refraction of –5.00 x –1.75 x 180, with a UCVA of 20/1000 , and a BSCVA of 20/20 . The left eye was intentionally undercorrected for monovision with a target refraction of –1.75D MRSE. The postoperative course of the left eye was unremarkable except for the notation of a 2-line loss in distance BSCVA reported at the 6-month visit. At 6 months postoperatively, the manifest refraction was –2.50 x 0.00 x 0, with distance UCVA of 20/400 and distance BSCVA of 20/30, which is consistent with the monovision treatment performed in this eye.

(C-R) 2007: C-R is a 53 year old female who underwent unremarkable bilateral LASIK surgery on the right and left eyes with the Nevyas Excimer Laser on 5/31/2001. Preoperatively, the right eye had a manifest refraction of –7.00 x –0.75 x 29 and the left eye had a manifest refraction of –8.75 x –1.00 x153. Preoperative UCVA was 20/1000 and BSCVA was 20/20 in both eyes. A monovision treatment was performed with the right eye targeted for plano and the left eye intentionally undercorrected to a target of –2.00 D. Postoperative course in the left eye was unremarkable except for the notation of punctate staining at 1 month post-LASIK. The right eye was noted to have punctate staining at 1 month and SPK at 6 months post-LASIK. The right eye also had a 2-line loss in BSCVA at 6 months postoperatively, with a manifest refraction of –1.50 x –0.75 x 58, UCVA of 20/70, and BSCVA of 20/30. BSCVA was unchanged in the left eye, and the eye had a manifest refraction of –3.25 x –0.25 x 165, UCVA of 20/100, and BSCVA of 20/20. Both eyes were retreated at 6 months post-LASIK using a commercially available laser to reverse the monovision treatment. At 3 months post-retreatment, the manifest refraction is +0.50 x –0.50 x 115 in the right eye and +1.00 x –0.75 x 90 in the left eye. Both eyes have an UCVA of 20/20 and BSCVA of 20/20.

(D-M) 2182/2183: D-M is a 38 year old male who underwent unremarkable bilateral LASIK surgery on the right and left eyes with the Nevyas Excimer Laser on 4/30/1998. Preoperatively, the right eye had a manifest refraction of –4.25 x –2.00 x 170 and the left eye had a manifest refraction of –4.25 x –2.00 x 11. Preoperative UCVA was 20/400 and BSCVA was 20/40 in both eyes. A monovision treatment was performed with the right eye targeted for –0.625 D and the left eye intentionally undercorrected to a target of –2.25 D. It should be noted that this patient is a difficult patient to refract. The patient is uncooperative in performing the refractive procedures and refuses to try to read smaller lines on the distance visual acuity chart. Losses in BSCVA ranged between 2 and 6 lines in the right eye and between 1 and 6 lines that are inconsistent with the small residual refractive errors measured at each visit. A hard contact lens was tried in the right eye at 1 month postoperatively in an attempt to improve the BSCVA. BSCVA was 20/60 at this 1-month visit and remained unchanged at 20/60 with the hard contact lens at 2 months postoperatively. At the 24-month end of study visit, the patient has a manifest refraction of –0.50 x –0.50 x 60 in the right eye and –1.00 x –0.25 x 45 in the left eye, with an UCVA of 20/100 and BSCVA of 20/80 (4-line loss in BSCVA) in each eye. We believe the loss in BSCVA experienced by this patient is directly linked to his unwillingness to perform the visual acuity testing as instructed and is not a true reflection of his visual outcome.

Subj: **Confirm this please**
Date: 8/7/02 3:08:20 PM Eastern Daylight Time
From: BSFant
To: Newyas

Rich,
Can you confirm the UCVA/BSCVA preop values for the following patients. Current values in the database are listed.

Joseph Mack	right eye	UCVA = 20/20	BSCVA = 20/400
Germaine Diehl	right eye	UCVA = 20/20	BSCVA = 20/200
William Smith	left eye	UCVA = 20/100	BSCVA = 20/100
Soo Eng	right eye	UCVA = 20/40	BSCVA = 20/50
Soo Eng	left eye	UCVA =20/200	BSCVA = 20/50

Thanks!

Barbara S. Fant, Pharm.D.
Clinical Research Consultants, Inc.
3307 Clifton Avenue
Cincinnati, Ohio 45220
PH: (513)-961-8200 FAX: (513)-961-2858

Founding Partner, Integrated Center For Service Development http://www.integratedcenter.com

4/1/02

IDE Patients having documented reduction in BCVA- Narrative explanation

Jacqueline Yeo- Previous to patient's OU LASIKprocedure patient had BCVA of 20/20 – OD, OS, OU. Two weeks after surgery she was best corrected to 20/25- OD, OS, OU. At the last visit on 1/21/02 after enhancement on both eyes she had BCVA of OD 20/25 + and OS 20/20-. We believe the reduction of BCVA was subjective error in patient responses.

Chris Wheeler- On 11/3/00 Mr. Wheeler had OD BCVA of 20/40 but on his latest visit 12/7/00 he had BCVA of 20/20. On 8/7/00 he had OS BCVA of 20/30 but on 12/4/00 he had BCVA of 20/25/+3. Mr. Wheeler had OD BCVA of 20/60 on 8/7/00 but as noted above his 12/7/00 BCVA was 20/20.

On 10/30/98 it was reported that Teresa Pavlin had a reduction of OS BCVA to 20/30 but on 5/26/00 she had BCVA of 20/25, we believe that this reduction was subjective error in patient reponses.

On 1/25/01 it was reported that Helen Onofrio had a reduction of her OD BCVA to 20/40. On 1/25/01 she had a refraction by another doctor in the practice who found BCVA of 20/25+ in her OD. We feel this might simply be doctor error in notation.

On 5/1/00 it was reported that Michael Nester had a reduction in his OS BCVA to 20/30 but yet on 3/26/01 his BCVA in his OS was 20/20-. We feel this might have been subjective error in patient responses.

On June 18, 1999 it was reported that Meghan Hoerner had a reduction in her OS BCVA to 20/30 but on 6/26/99 her BCVA in the OS was 20/25+1 and was 20/20 on 7/14/00. We believe this must be subjective error in patient responses.

On 3/4/99 it was reported by a comanaging doctor that Colette Harlan had a reduction in her BCVA OS to 20/40. On 5/6/99 Ms. Harlan was in our office and had OS BCVA of 20/20 therefore this reduction must have either been doctor transcription error or a subjective error in patient responses.

On 4/21/01 Eleanor Forstater had a reduction in her OD BCVA to 20/30 –2 but on 3/9/02 her OD BCVA was 20/25 +3. We feel this must have been subjective error in patient responses.

On 9/30/99 it was reported that Soo Eng had a reduction of BCVA in her OD to 20/60. Her preoperative BCVA was 20/30 and on 8/31/01 her OD BCVA was 20/25. This must have been subjective error in patient responses.

On 1/19/00 it was reported by a comanaging doctor that Bruce Dizengoff had a reduction in his OS BCVA to 20/30. In our office on 2/1/01 Mr. Dizengoff's OS BCVA was reported as 20/20-, this could have been doctor transcription error or subjective error in patient responses.

On 9/11/00 Pierre DeMauriac had a reported reduction in his OS BCVA to 20/30. On 1/22/01 Mr. DeMauriac's OS BCVA was 20/20+, therefore we believe this reduction in BCVA could have been technician error (technician did the refraction) or subjective error in patient responses since there was not a decrease in BCVA before or after the 9/1100 visit.

On June 29, 1998 there was a reported reduction in Raymond Bogdan's OS BCVA to 20/30 but on 10/5/00 his BCVA was 20/20. We feel there was possibly subjective error in patient responses on June 29,1998.

On June 29, 1998 and August 31, 1998 it was reported that John Welty had a reduction of his OD BCVA to 20/30. On A[illegible] Mr. Welty was examined and his BCVA was found to be 20/25 +2 in his OD therefore we feel this must have been subjective error in patient responses that led to the report of reduced OD BCVA.

On 12/21/00 it was reported that Al Pagnelli had a reduction in his OS BCVA to 20/30 but at his last visit with us his OS BCVA was 20/20 so we feel that this reduction must have been subjective error in patient responses.

On 2/21/01 it was reported that Regina Albert had a reduction in her OS BCVA to 20/25 and on 1/8/01 her OD to 20/25. On her last visit to our office her BCVA in her OD was 20/20 and her OS was 20/20. Therefore we feel this must have been subjective error in patient responses.

On 2/15/00 it was reported that Linda Aaron had a reduction in her OS BCVA to 20/60 at a comanaging doctor" office. On 2/21/00 she visited our office and we found her OS BCVA to be 20/20 so we feel this might have been doctor transcription error or subjective error in patient responses since before or after 2/15/00 there was no dramatic reduction in BCVA.

On 4/4/98, 7/8/98 and 8/5/98 it was noted that Keith Wills had a reduction in his OD BCVA to 20/40. On 6/12.99 we found OD BCVA of 20/25 + so feel this might have been subjective error in patient responses during the previous visits.

On January 4, 2001 it was reported that Ver Vang had a reduction of his OD BCVA to 20/25 from 20/15. This may have been a result of a small central island OD

On 11/19/98, 3/13/99 and 7/22/99 it was reported that John Tumolo had a reduction in his OD BCVA to 20/30. We feel this was as a result of an approximately 1mm inferior temporal decentration in ablation.

On 3/16/00 and 10/25/00 it was reported that Daniel Paige had a reduction in his OD BCVA to 20/30. We feel this might have been as a result of a small central island.

On 7/19/01 it was reported that [illegible]n Angstadt had a reduction in her OD BCVA to 20/30. We feel this might have been as a result of a small central island.

BSCVA To Check	PreopBSCVA	Last	First	Eye	F/UpDate	SxID	SchVisitID	VASC	RXsphere	RXCyl	RXAxis	BCVA
>20/40, check pre and post BSCVA	20	Aaron	Linda	OS	15-Feb-00	1236	6 Month	100	0.00	-1.75	170	60
check pre and post BSCVA	15	Albert	Regina	OD	08-Jan-01	1022	18 Month	25	1.25	-0.75	158	25
check pre and post BSCVA	15	Albert	Regina	OS	21-Feb-01	1021	18 Month	30	-0.50	-0.50	65	25
check pre and post BSCVA	20	Angstadt	Patricia	OD	19-Jul-01	1714	6 Month	30	0.50	-0.75	150	30
check pre and post BSCVA	20	Bagnoli	Al	OS	21-Dec-00	1529	6 Month	70	-2.25	-0.50	90	30
check pre and post BSCVA	20	Bogdan	Raymond	OS	29-Jun-98	275	9 Month	100	6.50	-1.25	120	30
check pre and post BSCVA	20	Chung	Suk Ling	OD	21-Dec-00	1457	6 Month	200	-2.25	-0.25	157	40
check pre and post BSCVA	20	DeMauriac	Pierre	OS	11-Sep-00	1019	12 Month	30	0.50	-1.50	107	30
check pre and post BSCVA	20	Dizengoff	Bruce	OS	19-Jan-00	1111	6 Month	80	-2.00	-0.50	15	30
>20/40, check pre and post BSCVA	30	Eng	Soo	OD	30-Sep-99	347	24 Month	70	0.25	-1.50	122	60
check pre and post BSCVA	20	Forstater	Eleanor	OD	21-Apr-01	1599	6 Month	30	-0.25	-0.75	143	30
check pre and post BSCVA	20	Harlan	Colette	OS	04-Mar-99	612	6 Month	70	-1.00	-0.50	90	40
check pre and post BSCVA	20	Hoerner	Meghan	OS	18-Jun-99	238	6 Month	60	-2.00	-0.25	45	30
check pre and post BSCVA	20	Nester	Michael	OS	01-May-00	928	12 Month	30	-0.75	-0.50	100	30
check pre and post BSCVA	25	Onofrio	Helen	OD	25-Jan-01	1544	6 Month	50	-1.00	-0.25	45	40
check pre and post BSCVA	20	Paige	Daniel	OD	16-Mar-00	1108	6 Month	30	-0.25	-1.00	105	30

BSCVA To Check	PreopBSCVA	Last	First	Eye	F/UpDate	SxID	SchVisitID	VASC	RXsphere	RXCyl	RXAxis	BCVA
check pre and post BSCVA	20	Paige	Daniel	OD	25-Oct-00	1108	12 Month	40	-0.75	0.00	0	30
check pre and post BSCVA	20	Paige	Daniel	OS	16-Mar-00	1107	6 Month	30	1.00	-0.25	130	30
check pre and post BSCVA	20	Paige	Daniel	OS	25-Oct-00	1107	12 Month	25	0.75	0.00	0	30
check pre and post BSCVA	20	Pavlin	Teresa	OS	30-Oct-98	218	9 Month	40	-1.50	-1.00	105	30
check pre and post BSCVA	20	Sawn	Walter	OS	17-Aug-98	407	6 Month	40	0.50	-0.25	90	30
check pre and post BSCVA	20	Tumolo	John	OD	19-Nov-98	261	12 Month	60	-1.00	-0.75	60	30
check pre and post BSCVA	20	Tumolo	John	OD	13-Mar-99	261	18 Month	30	-0.25	-0.50	65	30
check pre and post BSCVA	20	Tumolo	John	OD	22-Jul-99	261	24 Month	70	-0.50	-0.75	75	30
check pre and post BSCVA	15	Vang	Yer	OD	04-Jan-01	1284	12 Month	80	-1.50	-0.75	15	25
check pre and post BSCVA	20	Waddell	Lois	OD	08-Mar-00	826	6 Month	50	1.75	-1.25	135	30
check pre and post BSCVA	20	Waddell	Lois	OS	08-Mar-00	825	6 Month	70	-1.00	-0.50	15	40
check pre and post BSCVA	20	Welty	John	OD	29-Jun-98	325	6 Month	30	0.25	-0.75	95	30
check pre and post BSCVA	20	Welty	John	OD	31-Aug-98	325	9 Month	40	-0.25	-0.75	50	30
>20/40, check pre and post BSCVA	20	Wheeler	Chris	OD	07-Aug-00	1192	9 Month	200	0.00	-3.75	30	60
check pre and post BSCVA	20	Wheeler	Chris	OD	03-Nov-00	1192	12 Month	30	1.75	-2.25	45	40
check pre and post BSCVA	20	Wheeler	Chris	OS	07-Aug-00	1191	9 Month	100	0.25	-1.75	140	30

BSCVA To Check	PreopBSCVA	Last	First	Eye	F/UpDate	SxID	SchVisitID	VASC	RXsphere	RXCyl	RXAxis	BCVA	
heck pre and post SCVA	0	20 Wills	Keith	OD	04-Apr-98	278	6 Month	40	1.25	-2.00	110	40	✓
heck pre and post SCVA	0	20 Wills	Keith	OD	08-Jul-98	278	9 Month	100	2.75	-0.50	101	40	✓
heck pre and post SCVA	0	20 Wills	Keith	OD	05-Aug-98	278	12 Month	70	2.00	0.00	0	40	✓
heck pre and post SCVA	0	20 Wills	Keith	OS	04-Apr-98	277	6 Month	100	-1.50	-1.50	140	30	✓
heck pre and post SCVA	0	20 Wills	Keith	OS	01-Jun-98	277	9 Month	100	-1.25	-2.00	137	30	✓
heck pre and post SCVA	✓ ✓	20 Yeo	Jacqueline	OD	28-Jun-01	1499	12 Month	60	-4.00	-0.50	135	30	✓ ✓
heck pre and post SCVA	✓ ✓	20 Yeo	Jacqueline	OS	28-Jun-01	1500	12 Month	60	-1.75	-0.25	135	30	

NYA 00227

2/26/00

HJN:

On top of the your refrigerator are the charts that have been pulled for reduction in BCVA, per Fant. I've attached to each chart the "rationalization" of decreased BCVA for each patient that improved after the date chosen by Fant. I couldn't "rationalize" for Angstadt, Chung, Paige, Sawn, Tumolo, Vang, Waddell and Wills. In addition I didn't develop a reason for BCVA decrease on any patients because of technical error (decentration, SPK, etc.). Please review my work and edit and return to my desk so that I might finalize this part of the chart review. I've forwarded the reasons for decrease to Fant to see if this is what she would need in an FDA audit.

Rich

IDE Patients having documented reduction in BCVA- Narrative explanation

Jacqueline Yeo- Previous to patient's OU LASIKprocedure patient had BCVA of 20/20 – OD, OS, OU. Two weeks after surgery she was best corrected to 20/25- OD, OS, OU. At the last visit on 1/21/02 after enhancement on both eyes she had BCVA of OD 20/25 + and OS 20/20-. We believe the reduction of BCVA was subjective error in patient responses.

Chris Wheeler- On 11/3/00 Mr. Wheeler had OD BCVA of 20/40 but on his latest visit 12/7/00 he had BCVA of 20/20. On 8/7/00 he had OS BCVA of 20/30 but on 12/4/00 he had BCVA of 20/25/+3. Mr. Wheeler had OD BCVA of 20/60 on 8/7/00 but as noted above his 12/7/00 BCVA was 20/20.

On 10/30/98 it was reported that Teresa Pavlin had a reduction of OS BCVA to 20/30 but on 5/26/00 she had BCVA of 20/25, we believe that this reduction was subjective error in patient reponses.

On 1/25/01 it was reported that Helen Onofrio had a reduction of her OD BCVA to 20/40. On 1/25/01 she had a refraction by another doctor in the practice who found BCVA of 20/25+ in her OD. We feel this might simply be doctor error in notation.

On 5/1/00 it was reported that Michael Nester had a reduction in his OS BCVA to 20/30 but yet on 3/26/01 his BCVA in his OS was 20/20-. We feel this might have been subjective error in patient responses.

On June 18, 1999 it was reported that Meghan Hoerner had a reduction in her OS BCVA to 20/30 but on 6/26/99 her BCVA in the OS was 20/25+1. We believe this must be subjective error in patient responses.

On 3/4/99 it was reported by a comanaging doctor that Colette Harlan had a reduction in her BCVA OS to 20/40. On 5/6/99 Ms. Harlan was in our office and had OS BCVA of 20/20 therefore this reduction must have either been doctor transcription error or a subjective error in patient responses.

On 4/21/01 Eleanor Forstater had a reduction in her OD BCVA to 20/30 –2 but on 3/9/02 her OD BCVA was 20/25 +3. We feel this must have been subjective error in patient responses.

On 9/30/99 it was reported that Soo Eng had a reduction of BCVA in her OD to 20/60. Her preoperative BCVA was 20/30 and on 8/31/01 her OD BCVA was 20/25. This must have been subjective error in patient responses.

On 1/19/00 it was reported by a comanaging doctor that Bruce Dizengoff had a reduction in his OS BCVA to 20/30. In our office on 2/1/01 Mr. Dizengoff's OS BCVA was reported as 20/20-, this could have been doctor transcription error or subjective error in patient responses.

On 9/11/00 Pierre DeMauriac had a reported reduction in his OS BCVA to 20/30. On 1/22/01 Mr. DeMauriac's OS BCVA of 20/20+, therefore we believe this reduction in BCVA could have been technician error (technician did the refraction) or subjective error in patient responses since there was not a decrease in BCVA before or after the 9/1100 visit.

On June 29, 1998 there was a reported reduction in Raymond Bogdan's OS BCVA to 20/30 but on 10/5/00 his BCVA was 20/20. We feel there was possibly subjective error in patient responses on June 29,1998.

On June 29, 1998 and August 31, 1998 it was reported that John Welty had a reduction of his OD BCVA to 20/30. On April 19,1999 Mr. Welty was examined and his BCVA was found to be 20/25 +2 in his OD therefore we feel this must have been subjective error in patient responses that led to the report of reduced OD BCVA.

On 12/21/00 it was reported that Al Bagnoli had a reduction in his OS BCVA to 20/30 but at his last visit with us his OS BCVA was 20/20- so we feel that this reduction must have been subjective error in patient responses.

On 2/21/01 it was reported that Regina Albert had a reduction in her OS BCVA to 20/25 and on 1/8/01 her OD to 20/25. On the last visit to our office her BCVA in her OD was 20/20 and her OS was 20/20. Therefore we feel this must have been subjective error in patient responses.

On 2/15/00 it was reported that Linda Aaron had a reduction in her OS BCVA to 20/60 at a comanaging doctor'' office. On 2/21/00 she visited our office and we found her OS BCVA to be 20/20 so we feel this might have been doctor transcription error or subjective error in patient responses since before or after 2/15/00 there was no dramatic reduction in BCVA.

Nevyas Eye Associates Quality Manual

MANAGEMENT RESPONSIBILITY

Policy

The executive management at Nevyas Eye Associates, Inc. is ultimately responsible for implementing and maintaining the quality system. Executive management defines the quality policy and objectives, determines the organizational structure and responsibilities for quality related activities, and provides the necessary resources required to maintain the quality system. Management reviews the suitability and effectiveness of the quality system and objectives on a periodic basis.

Quality Policy

Executive management documents the quality policy and quality objectives. Nevyas Eye Associates, Inc. is committed to continuous measured quality improvement. All employees receive training on the quality policy and objectives when they are hired and at training sessions held on a periodic basis.

Organization, Responsibility and Authority

The interrelationship of personnel who manage, perform, and verify work affecting quality is outlined in the organizational chart in this section. All personnel at Nevyas Eye Associates are responsible for maintaining and supporting the quality system. Specific responsibilities are explained in functional job descriptions.

Resources

Executive management is responsible for providing the necessary resources to implement and maintain the quality system. This includes assigning trained personnel to activities affecting product quality and verification activities, including contracted internal quality audits.

Management Representative

Nevyas Eye Associates has appointed the Director of Inter-professional Relations (IR) as the management representative. The management representative has the authority and responsibility to ensure that the quality system is established, implemented, maintained; and complies with 21 CFR Part 820, as applicable and appropriate. The management representative is responsible for reporting on the performance of the quality system to Dr. Herbert Nevyas.

Management Review

- Executive management meets annually to review the quality system. Management reviews may be held more frequently when necessary. The review is coordinated by the Director of IR.

- Minutes of the review, including the date and individuals present are kept on file.
- Reviews are attended by at least Dr. Nevyas and the Director of IR.
- The agenda is prepared by the Management Representative. The suitability and effectiveness of the quality system is assessed by reviewing the following: quality performance data, internal quality audit program, customer response, regulatory issues, corrective and preventive actions, the quality policy, and the effectiveness of the quality system.
- Other information may be presented at the discretion of the Director of IR.

QUALITY SYSTEM

Policy

Nevyas Eye Associates maintains a documented quality' system designed to fulfill the requirements of the Quality System Regulation. The quality system is documented in this quality manual, standard operating procedures, master device records, device history records, parts lists, and equipment operating procedures. The quality system defines the control of design information, incoming materials, production processes, in process testing, and testing / inspections.

Quality System Documentation

- The quality system is defined in the quality manual, standard operating procedures, device master record, design history file, parts lists, and equipment operating procedures.
- These documents define a quality system that complies with the Quality System Regulation as applicable to Nevyas Eye Associates. Document Control explains the purpose of these documents and the methods for controlling their distribution and use.

Quality System Implementation

- All personnel who manage, perform, and verify work affecting quality are responsible for implementing the quality system. The Director of IR is responsible for coordinating, monitoring, and auditing the system.

INTERNAL QUALITY AUDITS

Policy

Internal audits are conducted. All areas of the Quality System are audited at least once per year. Internal audits are used to measure compliance to and the effectiveness of the Quality System. Audits are scheduled on the basis of status and

importance of the individual areas. Audits are conducted by personnel independent of the activity being audited, i.e. contracted to a third party.

Planning and Scheduling

- The internal audit plan and schedule is established by the Director of IR. All areas of the Quality System are audited at least once per year. These audits are divided up by functional areas. The audit schedule can be revised and updated at any time in order to focus on important or deficient areas, as applicable.

Auditors

- All audits are conducted by an outside consultant to Nevyas Eye Associates.

Conducting the Audit

- Objective evidence is compiled to show the level of compliance to the documented quality system and to determine the effectiveness of the quality system.

- The audit report contains the dates of the audit, the personnel and areas involved, and documentation of the non-conformances and observations found. Corrective action and preventive action requests are issued for all non-conformances and presented to the director and supervisor of the area in which they occurred. Auditors try to minimize disruptions to the audited activities.

Corrective Action and Follow Up Activities

- The Director of IR responds to the corrective action and preventive action requests and signs the audit report. The auditor and auditee determine acceptable due dates for each corrective action.

- Corrective action is completed in a timely manner. Implementation and effectiveness of the corrective action is verified by a follow up audit, where necessary.

- All audit reports are presented for management review. Audit reports are filed in a safe and secure manner.

TRAINING

Policy

Human resource, quality system and safety training is given to all employees. Individual Managers and Supervisors are responsible for training each employee in their job functions. Personnel are qualified based on education, training, and experience. Training files are maintained for all personnel as a quality system record.

Identification of Training Needs

- The Director of IR determines the general training needs of all employees. Employees are qualified based on education, training, and experience.
- The Director of IR is responsible for determining the specific training needs of the personnel in their areas and for establishing departmental training programs.
- Supervisors and individuals are responsible for job specific training in their areas.
- Training needs are also identified from nonconforming product reports, corrective and preventive action requests, complaints and other sources of quality data.

Training Records

- The Director of IR maintains training files for all of the employees. Training files contain documentation of qualifications, on the job training, and outside training courses completed.

DESIGN CONTROL

Note: This quality manual supports the one Nevyas laser device on site. The device is presently in use and another device being designed, constructed, etc. is not anticipated. Therefore, these are the only sections of the Design Controls GMPs that are applicable:

Design Validation

- Design validation consists of performance testing intended to demonstrate that the product specifications meet the final intended use of the device. Validation is conducted using production devices or their equivalents under defined operating conditions. Software validation is required.
- Validation testing is conducted under actual or simulated use conditions that will require clinical trials.

Design Approval and Release

- Design approval and release consists of officially documenting the review board's concurrence that changes to product design meet all defined requirements and may be released for use by Nevyas Eye Associates as appropriate.

Design Changes

- Changes during the design process are reviewed and approved by Dr. Nevyas and the Director of IR before they are implemented.
- The design requirements are modified to incorporate changes. Design changes are verified and validated when appropriate.

Design History File

- The Design History File (DHF) is a compilation of written documents and records, which describe the design history of a finished device. A DHF will be compiled and maintained for this device. The Director of IR maintains the DHF through the history of the device.
- The DHF demonstrates that the device was developed according to plan.

DOCUMENT AND DATA CONTROL

Policy

All documents are reviewed and approved before they are issued. Documents and document changes are approved by designated individuals. Documents are always available in the areas where they are used. Obsolete documents are removed from points of use. A master list of approved documents is maintained in document control. A history of document changes is kept as part of each document

Quality System Documentation

At Nevyas Eye Associates quality system documentation consists of the following types of documents:
Quality Manual, Device Master Records, Standard Operating Procedures, Quality Procedures, Component Specifications, Parts Lists, Labeling Specifications, Brochure Specifications, Standards, Design History File and other technical reference materials

Document and Data Control

- New documents and document changes may be initiated by all employees at Nevyas. Documents are only issued by document control. Documents are reviewed and approved by designated individuals/areas before they are issued. Documents are available in the areas where they will be used. Obsolete documents are removed promptly from all points of use. Document control maintains copies of obsolete and superseded documents. These documents are marked and segregated from approved documents.

- A master list of all documents is maintained in document control. This list identifies the current revision status of all documents.

- Electronic documents and databases are backed up on a regular basis by Nevyas Eye Associates.

Document and Data Changes

- Changes to documents are reviewed and approved by the same functions that reviewed and approved the original document. Validations, justifications, and pertinent background information are circulated with the document during the approval process.
- Changes to documents are indicated on the cover sheet and in the attached description of change history. Cover sheets to documents contain the current changes to the document, the change author, the effective date of the change, and the signatures of the approving individuals.

PURCHASING CONTROLS

Policy

Nevyas Eye Associates evaluates the capability and quality systems of its suppliers and subcontractors and purchases only from the approved suppliers. Supplier performance is monitored. Purchasing documents specify the requirements of purchased material and are reviewed and approved before orders are placed. The Director of IR is ultimately responsible for ensuring that all purchased materials and services that have an impact on the quality of finished products and services conform to specified requirements.

Evaluation of Suppliers

- The Director of IR is responsible for approving suppliers/subcontractors. Suppliers are selected based on defined criteria related to a *supplier's/subcontractor's ability to meet Nevyas' requirements for quality, cost,* and delivery. Critical materials and services may only be purchased from suppliers on the approved component specification.

- Purchasing maintains a record of each supplier's aberrant performance and capability to meet Nevyas Eye Associates requirements.

- Suppliers with inadequate performance are requested to implement corrective action and may be removed as approved suppliers if there is no improvement.

Purchasing Data

- The Director of IR is responsible for ensuring that purchase orders are reviewed and approved for adequacy of specified requirements prior to ordering, i.e., supplier/subcontractor is approved, product is defined, quality requirements are stated, packaging and delivery requirements are specified.

- Buyers are responsible for ensuring that purchasing documents contain data clearly and completely describing the product ordered. In cases where the purchase order is not sent to the customer or when the purchasing information is sent via fax, the buyer verifies that all information is correct before it is sent.

- Copies of purchasing documents are retained to allow traceability to the raw materials and components / parts.

Verification of Purchased Product

- It is the policy at Nevyas Eye Associates, where specified in the contract, that the purchaser or his representative shall be afforded the right to verify at the source or upon receipt that purchased product conforms to specified requirements. Verification by the purchaser shall not absolve the supplier of the responsibility to provide acceptable product nor shall it preclude subsequent rejection.

- Whenever possible, it is specified that suppliers/subcontractors agree to notify Nevyas Eye Associates of any changes to purchased materials, so that the affect of the changes on finished product quality may be determined.

PRODUCT IDENTIFICATION & TRACEABILITY

Policy

Incoming materials and components are assigned unique numbers from an approved component specification or off-the-shelf catalogue when they are received. When assemblies, devices and components are made they are assigned a unique Nevyas Eye Associates lot number. Nevyas Eye Associates keeps Design History changes which track what materials are used in each lot.

Product Identification

- Materials and components that become part of Nevyas Eye Associate's device have a unique number from an approved component specification when they are received. This identification number and the manufacturers lot number are used to identify materials utilized in production processes.

- The Nevyas device is identified by name and serial number.

- Release status is controlled.

Traceability

- Records are maintained to track all materials, components, testing, inspection, environmental conditions, and personnel involved in the maintenance and servicing of the device.

PROCESS CONTROL

Device repair, preventive maintenance and part replacements are carried out under controlled conditions using documented procedures. Device procedures contain criteria for workmanship. Device testing equipment is calibrated and maintained to ensure functionality. Personnel are made aware of practices that could affect safety and product quality. Processes that can not be fully verified by testing and inspection are validated. Software used in process control and the device is validated.

Process Controls (Servicing, Maintenance and Repair only)

- Dr. Nevyas and the Director of IR are responsible for ensuring that these above processes are identified, planned, and executed under controlled conditions.
- Written procedures and instructions are used to ensure that processes that have a direct affect on the device's quality are carried out in a uniform manner. When it becomes necessary to deviate from procedures, all deviations are approved before any design activities are performed.
- These repair, replacement and preventive maintenance processes are controlled and monitored. In-process testing is performed at key points before the device is released for continued use by Nevyas Eye Associates.

Production and Process Changes

- Changes to methods, procedures, and specifications are reviewed and approved by the same people who initially approved the process before incorporation into production processes. Verification and validation are performed when changes are made to production processes, when necessary.
- When temporary changes to processes or specifications are required, they are documented and approved on a deviation request.

Environmental Controls

- Environmental conditions are monitored in areas where they could adversely affect device quality. There are no environmental requirements for this device.

Personnel

- Personnel are trained in their job functions and made aware of personal practices, which could affect product quality and / or personnel safety.

Contamination Control

- The Director of IR is responsible for ensuring that procedures are written and followed for establishing and maintaining sanitation and cleaning programs for facilities and equipment used in support of this device.

Buildings

- The Director of IR is responsible for ensuring that there is adequate space and a suitable design of work areas to prevent mix-ups of incoming parts and gases.

Equipment

- Equipment is regularly maintained and calibrated. The Director of IR assigns a maintenance and calibration schedule for the device.
- The Director of IR maintains files of all calibration and maintenance activities. Equipment is regularly inspected to assure that preventive maintenance has been completed. The device is calibrated prior to each use.

Process Validation

- All equipment that affect the quality of Nevyas Eye Associates device are verified and / or validated to ensure proper control and function. The device is calibrated prior to each use.
- Design validation of device changes is achieved as necessary. A new design is not released for use until it has been fully verified and validated.
- When computer software is used in production processes, it is validated according to its intended use. Changes to software are validated before they are used.
- All validations are carried out according to a validation protocol that is approved before use. All validation results and activities are documented in a validation report.

INSPECTION, MEASURING & TEST EQUIPMENT

Policy

Equipment is selected based upon the measurement and accuracy needs the device. All calibration standards used for equipment are traceable to national standards

(NIST). The calibration and maintenance status is clearly indicated on each piece of equipment. All employees are responsible for removing past due and uncalibrated equipment from service and bringing it to the attention of the Director of IR. The location and use of calibrated equipment is always controlled.

Control of Equipment

- The Director of IR is responsible for ensuring that all inspection, measuring, and test equipment used in testing is controlled, calibrated, and maintained according to procedures.
- Employees in the production, quality control, and product development areas do not use uncalibrated or past due equipment.
- Each piece of equipment has its own documented procedure and schedule for certifying its accuracy when used in the manufacturing process. "Uncalibrated" and "maintenance only" as needed equipment is clearly labeled. Inspection, measuring, and test equipment used to perform functional testing is calibrated regularly.
- The calibration /maintenance log documents the chronological history of all calibration and preventive maintenance activities and is maintained by the Director of IR.
- The date the calibration/maintenance was performed, the person who performed it, and the next due date is indicated on or near each piece of equipment.
- The Nevyas device is calibrated prior to each use.

Measurement Identification and Selection of Equipment

- Equipment is selected based on the measurement and accuracy needs of the device. Equipment is verified and validated to ensure that it is suitable for its intended use.

Equipment Calibration and Maintenance

- All equipment is marked or tagged with its assigned asset number and is labeled with its calibration and maintenance status.
- Internal standards that are utilized to verify the accuracy of inspection instruments are regularly calibrated by outside labs. When possible, calibration standards are traceable to the National Institute of Standards and Technology (NIST). All inspection, measuring, and test equipment that is not in current calibration is removed from the device area (s). New equipment or equipment with a past due calibration date is segregated to prevent use until the calibration has been completed.

- Calibration activity that discloses the potential for discrepant material results in the initiation of a nonconforming product report for the purpose of determining whether or not the potential was realized.

Validation of Test Software

- All test hardware and software used for inspection activities are subject to the same requirements as listed above for inspection, measuring, and test equipment.

Control of a Nonconforming Product / Services

Policy

- When the device is not operational it is identified to prevent it from unintended use.
- All nonconformances are evaluated and the responsibility for disposition is defined and documented
- Dr. Nevyas and the Director of IR are made aware of all nonconformities.

Identification and Control of Nonconforming Product

- All employees at Nevyas Eye Associates are responsible for identifying nonconformances concerning the device
- Nonconformance can be applied to any raw material, component, assembly or the device that fails to conform to specified requirements.
- Nonconformances are segregated and labeled until the nonconformity is evaluated and the disposition approved. Only Dr. Nevyas or the Director of IR can release the device for use.
- All nonconformances are documented no matter how insignificant they may seem or how easily they can be reworked. Each non-conformity is given a unique number and all activities are tracked.
- Dr. Nevyas and the Director of IR are made aware of all nonconformities.

Review and Disposition of Nonconformances

- Nevyas Eye Associates are responsible for all nonconformities and the preliminary investigation and identification of the root cause. In cases where the root cause is not easily identifiable, a formal investigation is initiated by the Director of IR.
- All dispositions are reviewed and approved by Dr. Nevyas. A justification of the disposition is recorded.
- Nonconformity reports are not closed until the investigations and corrective actions associated with it are completed.

Control of the Device when Repair is Required

- When the device is approved for repair, the repair procedure will be documented as such.
- All repairs will be reinspected, documented and approved to insure that device meets current approved specifications.
- Repair activities are documented in the device master record.

CORRECTIVE AND PREVENTIVE ACTION

Policy

Corrective and Preventive actions are initiated to fix and eliminate the causes of nonconformances and potential nonconformances. Corrective actions are also initiated to correct internal audit findings. All employees are encouraged to initiate preventive action requests when a potential nonconformity is observed. All customer complaints are documented and given a unique tracking number. Product performance related complaints are tracked and resolved through the customer complaint system.

Corrective Action

- Corrective action is taken when a nonconformance is identified. Corrective actions are initiated to fix the root cause or causes that contributed to a non-conformity or in response to internal audit observations. All corrective action requests receive a unique number and are documented.
- Proposed corrective actions are reviewed before they are implemented.
- Corrective actions are assigned a due date to ensure timely implementation.
- Corrective action that results in a process or design change is validated before implementation. All corrective actions are verified by the Director of IR. Nevyas keeps files on corrective action issues in order to ensure that actions are implemented and verified in a timely manner.
- Corrective actions are analyzed, trended and submitted for management review.

Preventive Action

- Preventive action is taken when the potential for a nonconformance is identified. The need for preventive action is determined by reviewing internal audit reports, customer complaints, nonconformity reports, and other sources of quality data.
- Trends are analyzed and action is taken. All employees are responsible for bringing potential nonconformity's to the attention of the Director of IR.

- Preventive actions are tracked and documented using the same system as corrective actions. Proposed preventive actions are reviewed and approved prior to implementation.
- Preventive action that results in a process or design change is validated before implementation.
- All preventive actions are verified by the Director of IR. The effectiveness of preventive action is verified during internal audits and is submitted for management review.

Customer Complaints

- Customer Complaints are initiated in response to all complaints related to product performance. Customer Complaints are assigned a unique tracking number by Nevyas.
- All Customer Complaints are documented and contains at least the following information: Date the complaint was received, customer name, address and phone number, product, catalog number, lot number, description of the complaint, determination of serious injury or death, complaint activity investigation, and review and approval signature of the Director of IR.
- Complaints involving the possible failure of the Nevyas device are investigated, unless an investigation has already been performed for a similar complaint. When an investigation is not determined to be necessary, a justification and the name of the person responsible are recorded on the form.
- Any complaints that may be reportable to the FDA are promptly reviewed, evaluated, and investigated. A Medical Device Report (MDR) is filed. The Director of IR is responsible for all communications and follow up with the FDA.
- Customer complaints are analyzed and trended. Corrective action is initiated as appropriate. All complaint information is submitted for management review.

CONTROL OF QUALITY RECORDS

Policy

Quality records demonstrate that procedures were performed correctly and that the specified level of product / service quality was achieved.

Device Master Record (DMR)

- The device master record was established and maintained for the device produced at Nevyas Eye Associates. The device master record contains or references the device specifications, production methods and specifications, Quality Control procedures, installation, maintenance, and servicing procedures where appropriate.

Device History Record (DHR)

- Multiple devices will not be built. Multiple DHRs are not applicable in this case.

Design History File (DHF)

- Design history files are established for each new/improved product as it is designed. It contains or references the records necessary to demonstrate that the design was developed in accordance with the approved design plan and appropriate regulations.

Quality System Record

- The quality system record refers to the location of procedures and the documentation of activities that are not specific to a particular type of device. The quality system record will be stored under document control in the Director of Nursing office.

Establishment of Records

- Quality Records are established to demonstrate conformance with specified requirements and the effective operation of the quality system. Records are usually established by the person who performs the activity that is being documented. When appropriate, quality records from subcontractors are part of the quality records.
- Records are stored in a manner to facilitate their retrieval. This includes appropriate labeling of containers and storage cabinets.
- Where required by contract, quality records will be made available for evaluation by the customer, the customer's representative and the FDA .

Storage and Retention Periods

- Records are stored in a manner to minimize deterioration and allow for timely retrieval. Electronic records are backed up on a regular basis.
- Device history records are maintained for the design and expected life of the product or a minimum of two years from the date of the release of the product for commercial distribution.
- Storage and retention periods of department specific documents and records has been determined to be seven years.
- Management review records, internal audit reports and other non-device specific documents are maintained for a period specified in their respective procedures.

INSTALLATION AND SERVICING

Policy

Installation and servicing procedures and instructions are documented. Service reports are reviewed and service information is passed on to the affected areas.

Installation

- Installation is performed according to documented procedures to ensure that the device functions properly. Inspection and test results are documented to demonstrate proper installation.

Servicing

- When servicing is specified by procedures and instructions are maintained to ensure that servicing activities meet specified requirements.
- Service reports are reviewed to assure that: servicing meets specified requirements, trends are noted and communicated to Dr. Nevyas.
- Service reports are documented and maintained by the Manager of Quality Assurance. Note: Service data is submitted for Dr. Nevyas for review in all cases.

STATISTICAL TECHNIQUES

Policy

The responsibility to establish methods and instructions for the application of trending and statistical analysis is assumed at Nevyas. All incoming materials, components, parts, etc. are 100% inspected prior to use.

Identification of Need

- Nevyas employees are responsible for identifying and determining where trending and statistical techniques are needed as related to customer complaints and MDR issues.
- They are also responsible for procedures to implement and control the application of trending and statistical techniques in this area.

Sampling Plans

- Sampling plans are based on 100% inspection of parts and components used to service, repair or preventatively maintain the device.

Clinical Research Consultants, Inc.
3928 North Cliff Lane • Cincinnati, Ohio 45220
Telephone: (513) 751-3637 • FAX: (513)-751-3773

MEMORANDUM

To: Richard Sterling -- Dr. Nevyas

From: Barbara Fant, Pharm.D.

Date: July 30, 1997

Subject: IRB Documents

Recent changes at FDA make it imperative that we get the IRB approval for your myopia protocol as soon as possible. If you already have conditional approval, you need this to start your study. If your IDE is under review, obtaining the IRB approval now will get you up and running with your study quicker.

Your myopia protocol and consent form are being sent to Schulman Associates IRB for review and approval. Enclosed is the investigator's guide for the IRB. Please complete the following documents that are contained in the investigator's guide and send them to me as soon as possible and I will forward them to Schulman's IRB:

1. Site questionnaire (Appendix II)
2. Sample Submission Letter (Appendix III)
3. Indemnity Agreement (Appendix V)

Please return by August 14.

NYA 00511

a professional association of 350 eye doctors in the Delaware Valley who have chosen us as their refractive surgeons of choice. We conduct many educational seminars for Delaware Valley eye doctors on the subject of refractive surgery, and we routinely comanage refractive surgical patients with them to provide better care and more convenience for our patients. We have constructed, with the help of laser engineers, an extremely fine excimer laser surgical system which utilizes the highest quality components and which can be controlled by the surgeon to provide the best and most individualized surgical results. We have invented a very special fixation system which improves the centration of the excimer laser ablation. Our results have been excellent.

How should I choose my eye surgeon?

It would be best to choose a surgeon who is highly skilled, highly experienced and well recommended. He or she should have recommendations from patients and particularly from doctors who are familiar with his/her work. He or she should not have a large malpractice experience. He or she should utilize an excimer laser in a true surgical operating room rather than a commercial office suite. You should meet with him or her and feel comfortable with his or her degree of expertise.

What is the advantage of having my refractive surgery in a fully licensed ambulatory surgical center such as The Delaware Valley Laser Surgery Institute?

Our ambulatory surgical center has fully equipped ophthalmic operating rooms which are available should any emergency surgery be required. The operating rooms are equipped with special air cleaners with finely filtering HEPA filters that reduce particulate matter in the air and thereby make it less likely that particulate matter will be trapped in the flap-corneal interface. Such particles can be irritating and can carry infection. The operating rooms have special flooring which does not allow dust to collect at the corners and is easily cleaned. We use powder-free gloves and our personnel wear scrub suits to reduce the possibility of contamination.

Some refractive surgery centers place their lasers in regular carpeted office suites in an office building. Such environments are conducive to high levels of particulate matter and fibers in the air and do not protect adequately against infection. Our operating rooms are carefully controlled as to particulate matter, temperature and humidity, making LASIK surgery safer and more precise.

What refractive errors can you correct?

With refractive surgery of one variety or another, we can correct almost any refractive error in existence. We are experienced in a number of procedures, not just one, and we utilize the procedure which is best for each patient. The majority of our refractive surgical patients do best with LASIK surgery which is performed in our own

surgical center. We correct myopia from -0.5 to -15 diopters and astigmatism from 0.5 to 7 diopters. We correct hyperopia from 0.5 to 5 diopters with hyperopic LASIK, and we can correct any degree of high myopia or high hyperopia with refractive lensectomy and intraocular lens implantation. We have corrected as much as 42 diopters of nearsightedness with refractive lensectomy and as much as 12 diopters of farsightedness. With astigmatic keratotomy we have corrected as much as 14 diopters of astigmatism.

Will I have any pain?

There is essentially no pain reported by most of our LASIK surgery patients. Some stretching of the eyelid is felt as the eyelid holder is put into position, and a transient feeling of pressure usually for less than a minute, is felt while the suction ring is placed for creating the corneal cap with microkeratome. Most people have just slight operative discomfort and no postoperative pain at all. We usually give a small amount of oral Valium prior to surgery to relax you.

Do you do both eyes at one time?

We usually perform LASIK on both eyes together, however in some cases, especially those of very high nearsightedness, we may perform the two procedures at two separate times. This also depends on the patient's preference. We always perform refractive lensectomy with the two eyes done at separate times, usually a week or two apart. Radial and astigmatic keratotomy are usually performed bilaterally.

What are the risks of refractive surgery?

The primary annoyance with LASIK is seeing halos around lights at night. This is more prominent in people with large pupils and less pronounced in people with relatively small pupils. We measure everyone's pupil with a "night vision" measuring device so that we can know the size of the pupil in the dark to enable us to warn patients with unusually large pupils that they may be subject to glare at night.

The extremely rare case of infection or retinal detachment has been reported at times around the world. We have never had either of these problems occur after refractive surgery in our center.

There is a relatively rare situation known as diffuse lamellar keratitis or "Sands of the Sahara" syndrome characterized by a sterile inflammation of the interface between the corneal cap and the deeper part of the cornea. We have seen a very mild case of this on only one occasion and have never seen another case or a more severe case. The one case which we saw responded very well to a short course of steroid eyedrops. We take great pains to clean all blades with acetone prior to using them in order to remove any machine oil residues which are thought to be one factor responsible for this condition.

A few cases of postoperative retinal hemorrhage have been reported, primarily in Korea where very large ablations for extremely high refractive errors, much larger than we will do, were performed. We have never seen such a case.

Refractive lensectomy entails all of the risks of cataract surgery including infection, inflammation and dislocation of the intraocular lens. However, we have never seen any of these problems with refractive lensectomy, and they're quite rare with modern cataract surgery in general, especially cataract surgery performed on a relatively clear lens. We use the latest technique of clear corneal, self-sealing, no suture surgery with "no needle" eyedrop anesthesia for most cases of refractive lensectomy.

What is RK?

Radial Keratotomy (RK) is one of a group of procedures that can be used to correct nearsightedness. There are many such procedures that as a group are called refractive surgery. RK gets its name from the fact that it involves making radial incisions on the edge of the cornea to cause it to bulge outward, flattening the center of the cornea. Which of the refractive surgery procedures is right for you is a decision that your surgeon will make in consultation with you after he or she has evaluated your needs.

Note: Since the introduction of the first refractive surgery technique in the 1970's, over two million people have had refractive surgery performed. The success record is impressive. The vast majority of these people have experienced correction to at least 20/40 without the need for glasses.

Will I have 20/20 vision after the procedure?

Having a successful experience with your refractive surgery begins with realistic expectations of what it can do. The purpose of the surgery is to enable you to perform many activities without glasses, not to give you 20/20 vision. While the vast majority of patients achieve at least 20/40 unaided vision, not everyone gains complete freedom from glasses. The goal of refractive surgery is to obtain uncorrected vision close to the same corrected vision as you have now using your glasses or contacts.

What is the procedure that uses a laser?

When people talk about using a laser for refractive surgery, they are referring most often to the excimer laser. This laser vaporizes corneal tissue instantaneously. There are two main ways of using the laser to correct nearsightedness. One is to flatten the cornea by removing tissue from the front of the cornea (Photorefractive Keratectomy (PRK). The second is to raise a very thin flap of the front of the cornea and to use the excimer laser to remove tissue from within the cornea rather than the surface (Laser in-situ keratomileusis or LASIK).

NYA 00669

Do you think I need refractive surgery?

Nobody needs refractive surgery. It is an elective procedure. Many people can benefit from it, however. Refractive surgery can make a person less dependent on contact lenses or glasses. This can be valuable from a quality of life standpoint and even in certain circumstances from a safety perspective, particularly in occupations where unimpaired eyesight is critical.

Will I be able to see without glasses after the procedure?

The majority of refractive surgery patients are able to perform most activities without glasses, but some may still need help for especially demanding vision situations (such as driving at night or reading stock market quotations). Also, you may still need reading glasses as you grow older. Your surgeon will give you more information on what results you can realistically expect.

How long will it take?

The procedure itself takes about ten minutes. There is some equipment setup and patient preparation time, but once everything is set up, it doesn't take very long at all.

How much does it cost?

Refractive surgery, depending on the procedure recommended for you can cost between $1500 to $2500 per eye. The fee covers all pre-operative services, the surgery itself and any enhancements needed in the first year of post-operative care. (It is rare to require further surgery after six months.) If needed, payment plans are available. The full details will be explained to you when you go for your evaluation by the surgeon.

Who will do the procedure and are they experienced?

The surgeons at Nevyas Eye Associates: Dr. Herbert Nevyas, Dr. Anita Nevyas-Wallace, or both. The surgeons are very experienced and prominent in their fields, with many years of experience in anterior segment surgery and refractive surgery. Their refractive surgery experience extends to all aspects of refractive surgery and not just one or two modalities.

Where will the procedure by done?

It will be performed next to Nevyas Eye Associates offices in Bala Cynwyd in the Delaware Valley Laser Surgery Institute. The DVLSI is the most modern and well-equipped private ophthalmological surgical facility in the Delaware Valley. It is fully accredited by the Accreditation Association for Ambulatory Health Care (AAAHC) and licensed by the State of Pennsylvania.

Can I change my mind after I go for this evaluation?

Yes, This is an elective procedure. You may change your mind at any time. Before you decide whether to have the procedure, we will explain the procedure to you, as well as possible complications and previous results. We want you to be fully informed so that you will have all the information you need to make an informed decision.

Why do I have to make out two checks before surgery?

Your surgeon and the comanaging doctor (Optometrist and Ophthalmologist)if you choose to be comanaged are independent professionals working together to manage the care of your eyes. We each bill separately for our portion of your services.

Will my insurance cover this procedure?

Most health insurance does not cover refractive surgeon. The procedure is considered elective and almost cosmetic in as much as anyone can continue to wear glasses. Enhancement of lifestyle does not count as medical necessity for most insurance companies. Medicare and some insurances will cover astigmatic keratotomy for astigmatism generated during surgery.

Am I a candidate for LASIK?

Anyone dependent on glasses and/or contact lenses, who is at least 18 years old can be considered a candidate. We are able to correct nearsightedness, farsightedness and/or astigmatism with LASIK. The best way for you to find out if you are a candidate for LASIK is to schedule an evaluation with Nevyas Eye Associates.

Why is LASIK the preferred procedure at this time?

The LASIK procedure is extremely accurate and treats a broader range of patients with a more rapid and more comfortable recovery time than other refractive procedures.

Am I awake during the procedure and will I feel any pain?

You are fully awake during the procedure. Your eyes will be numbed with topical eye drops so you should not feel any pain. Most patients report minimal discomfort, and report only a feeling of slight pressure during the procedure.

You may be given a mild sedative, but the majority of our patients do not need any medication.

How long is the recovery time and what should I expect during that time?

Recovery from LASIK is very rapid and is one of the reasons it is the preferred procedure. Immediately following the procedure, most

patients show marked improvement and within 12-24 hours have a return to normal function and can return to work the next day.

During the first week, you may notice some fluctuations in your vision which is normal and is part of the healing process. Night glare and halos may persist for the first few weeks but usually cease by the end of the two to three month healing process.

Is LASIK considered permanent or does it need to be repeated?

LASIK has undergone numerous clinical trials and has been done for years in Canada and Europe. Patients that have had this procedure several years ago are still enjoying remarkable vision. NEA feels so strongly that LASIK is permanent and we offer to do any additional laser treatments at no cost to you. Some patients do not require full correction with the initial procedure and may have a need for an enhancement. An enhancement is a secondary procedure where additional laser must be added to achieve the full correction. This is more common in patients who are moderately to extremely nearsighted or have a lot of astigmatism.

What are Intacs?

KeraVision Intacs corneal ring segments are two small, transparent crescents or arcs. Thay are composed of the same material that has been safely used for nearly 50 years in hard contact lenses and intraocular lenses used to treat patients with cataracts (clouding of the eye's natural lens of the eye). Since Intacs are placed in the outer edge of the cornea, the center of the cornea remains untouched. Intacs are meant to remain permanently within the cornea; however, they can be removed or replaced.

Who is a candidate for Intacs?

Intacs are currently available for people with mild myopia (nearsightedness) who have no more than .75 diopters of astigmatism. The best way to find out if you are a candidate for the procedure is to schedule an appointment with the surgeons of NEA so that he/she can evaluate your vision.

You may qualify for Intacs, if:

Your prescription for eyeglasses or contacts is between -1.00 and -3.00 diopters, with no more than .75 diopters of astigmatism. If you don't know your current prescription, we can schedule you for a (complimentary) examination and consultation;

You have healthy eyes, free from disease or injuries;

You have had stable vision for at least one year; and

You are at least 21 years of age.

Who it NOT a candidate for Intacs?

You should NOT have Intacs placed if:

You have autoimmune or immunodeficiency diseases (lupus, rheumatoid arthritis or AIDS, for example);

You are pregnant or nursing (6 months after delivery);

You have conditions of the eye that may increase the possibility of future problems; or

You are taking prescription medications that may affect corneal healing or your vision.

The surgeons of NEA will review your general medical history with you and will evaluate your eyes for any conditions that might suggest you should not have Intacs. It is important to advise NEA if you have had a herpes infection in your eyes or if you have insulin-dependent diabetes or other conditions that might affect wound healing. You should also bring a list of any prescription and over-the-counter medicines that you take.

What are Intacs made of?

Intacs are made of a special biocompatible plastic that has been safely used for nearly 50 years in contact lenses and in the intraocular lenses used to treat patients with cataracts. Intacs are designed for permanent placement in the eye, but they are also removable.

What is the difference between Intacs and other refractive procedures:

Intacs are designed to be placed in the outer edge of the cornea away from the "central optical zone." Because nearly all the light that reaches the retina must pass through the central optical zone, it is the part of your cornea most important for clear vision. Therefore, it is essential not to damage the central optical zone. The procedure for Intacs does not cut or remove tissue from the central optical zone. This makes the procedure quite different from refractive surgical procedures that permanently alter the central cornea. Intacs are also removable and replaceable.

How do Intacs work?

Simply, Intacs gently change the shape of your cornea to correct your vision. In the nearsighted eye, the curve of the cornea is too steep. Light rays entering the eye are bent too much and are focused in front of the retina instead of on it. As a result, things far away appear blurry. Intacs change the shape of the cornea, allowing the light rays to focus on the retina. But unlike laser surgery, which reshapes the cornea by removing tissue from the center, Intacs are placed in the outer edge leaving the central optical zone intact.

What is the central optical zone and why is it so important?

The central optical zone refers to the center area of your cornea. Virtually all light that enters your eye passes through the central optical zone in order to be focused. For this reason, the central optical zone is crucial to clear vision. Intacs corneal ring segments are specially designed to be placed in the outer edge of the cornea away from the central optical zone.

What's involved in the procedure?

Typically, patients are given a mild oral sedative and eyedrops to numb the eye before the procedure. A tiny opening, less than 2 mm is made near the upper edge of the cornea beneath the eyelid. Intacs are inserted through this opening so that they rest between the layers of tissue in the cornea, outside the central optical zone. This procedure usually takes about 15 minutes and is performed on an outpatient basis.

What are the risks?

As with any refractive surgical procedure, there are certain risks and complications. Clinical studies in the U.S. showed that infection, which is a risk with any surgical procedure, occurred 0.2% of the time with Intacs. Other adverse events included: shallow Intacs placement (0.2%); temporary loss of 2 lines of best corrected vision (0.2%); and anterior chamber perforation during surgery (0.4%). None of these events resulted in a permanent loss of vision. Other complications included: overcorrection, reduction in central corneal sensation, difficulty with night vision, undercorrection, induced astigmatism, blurry vision, double vision, corneal blood vessels, halos, glare, fluctuating distance vision and a reduction of 2 or more lines of best corrected vision. If the results of the procedure are not satisfactory, you may need to have your Intacs removed or replaced. The surgeons of NEA will be happy to discuss the potential risks and benefits in detail with you.

Is the procedure reversible?

Intacs are removable. While the Intacs are in your eye, it gently reshapes the corneal tissue, which causes the light rays to focus properly. But it doesn't touch the part of your cornea most critical for clear vision. Clinical data has shown that patients' refractions returned to their preoperative levels by 3 months following removal, in most cases. The patient's correctable vision was 20/20 or better in all cases following removal of Intacs.

Is the procedure painful?

Usually there is no pain associated with this procedure. You may experience some discomfort (typically a pressure sensation) that only

lasts for a couple of minutes. Topical anesthetic will be used to help alleviate any discomfort during the procedure.

Will I have a lot of pain following surgery?

You may experience some discomfort or pain in your eye following the procedure. You will be mildly sensitive to light and will have the feeling that something is in your eye for the first few days. Most patients describe their discomfort as moderate and it typically diminishes within 48 hours. Your doctor may recommend a medication to help ease your discomfort. Give your eyes plenty of rest. Taking a nap after the procedure may help to alleviate any discomfort you may have.

Will I be able to drive myself the day of surgery?

You should arrange for transportation the day of the procedure and to your next examination, since you should not drive immediately after the procedure. Your doctor will advise you when it is safe to resume driving.

After the procedure will I have to wear a shield?

Your doctor may recommend that you may wear an eye shield at night. The shield should be worn to protect your eye from irritation and injury, such as rubbing or scratching, while you sleep.

When will I be able to return to work/resume normal activities?

While some people return to work the day after surgery, we recommend you take the day after surgery off. Generally, you can expect to return to your normal daily routines within a few days.

How long does the procedure take?

The procedure takes approximately 15 minutes for one eye, and you go home the same day. The total procedure, including the pre-surgical preparation, is usually completed in less than one hour.

What can I expect my vision to be?

In U.S. clinical studies, 97% of patients saw 20/40 or better with Intacs; 74% saw 20/20 or better--the standard for good vision, and 53% saw 20/16 or better, a level that exceeds the standard for good vision. To better understand what your potential results might be, we can schedule a complimentary exam for you.

	DAY 1	MONTH 3	MONTH 12
UNCORRECTED VISION			
20/16	13%	49%	53%
20/20	34%	71%	74%
20/25	55%	86%	87%

NYA 00675

20/40 81% 97% 97%

In the first couple of months, you may experience some glare, starbursts, halos and fluctuating vision. This is normal and improves slowly throughout the postoperative period. In most patients, these symptoms improve when Intacs are placed in the second eye.

Will I still need glasses or contact lenses after the procedure?

Typically, patients no longer depend on glasses for correction of their distance vision. Some patients may still wear glasses for reasons specific to their situation. For example, Intacs does not correct presbyopia, so you may still need reading glasses. It is not recommended that a contact lens be worn on an eye that has Intacs.

How long do Intacs stay in the eye?

Intacs are intended to remain permanently in place without maintenance, yet a trained ophthalmic surgeon can easily remove them.

Can Intacs be felt once they are in place?

No. Intacs are not felt because they are placed in the cornea beneath the nerve endings.

Can Intacs be seen by the naked eye?

Intacs are barely noticeable to other people and their appearance in the eye is similar to a contact lens.

Can they dry out or get dirty like a contact lens?

No. Intacs are designed to remain permanently in placed within the cornea and don't require maintenance.

Could I have an allergic reaction to Intacs?

The material used for Intacs has a long history of being safely used in the eye. It has not been known to interact with eye tissue to produce an allergic reaction or other side effects, such as swelling or irritation.

What if my vision changes?

As you get older, your eyesight will change. If the Intacs you were given no longer provide the amount of correction you need, they may be removed or replaced. Your doctor will help you determine the best means to accommodate any changes in your vision.

What will my vision be like if I later want Intacs removed?

Intacs can be easily removed in a brief outpatient procedure. When Intacs were removed in U.S. Clinical studies, patients' vision returned to their preoperative levels, in most cases. This process

typically took three months. All patients' corrected vision was 20/20 or better following the removal of Intacs.

typically took three months. All patients' corrected vision was 20/20 or better following the removal of Intacs.

TESTIMONIALS

Andrew Kessler-

Why did you decide to have the LASIK procedure:

I lead a relatively active lifestyle. In addition to being a father, I'm a skier and a tennis player and I like to spend (obviously skiing) a lot of time outdoors. Coming indoors from outdoors in the winter, anyone who wears glasses has had the experience of having the condensation on their glasses, and just being able to be in the ocean, doing the things I want to do, glasses were an inconvenience.

With any surgery we know there's some risk involved, when you approached this, how did you weigh benefits against the risks?

Well, obviously what I was looking at was the opportunity to not have to wear glasses anymore but primarily I looked at all the potential operations that were available and I've been looking for a lot of years. I have the benefit of being the son of an optometrist, so for about the last fifteen years I've been looking for some way to avoid wearing my glasses and at some point it was made known to me that there was this LASIK procedure which has a very high level of success, for which I was a very good candidate.

After being through this procedure, what do you think?

I'm ecstatic. I'm also grateful to Dr. Nevyas-Wallace. Since I had the procedure, I am corrected glasses free. I am thrilled.

Dr. Tammy Schuler-

As an optometrist and someone who has had LASIK performed, what kind of legwork do you recommend to people when researching and deciding whether they should get this done and by whom.

Usually when patients are interested in refractive procedures, I recommend that they look for a surgeon that they feel comfortable with and also one that has experience. You should be comfortable with the person who performs the surgery because you will have concerns both from a vision standpoint and from an anxiety standpoint.

How do you feel about your results?

I am very very pleased. From the moment that I had the procedure I was 20/20 and I experienced very very little discomfort. I was told that I could anticipate a little bit of glare night because I have a large pupil size. I did experience glare at night however it was never hindering because my vision was clear. After about three months it totally dissipated and is now gone.

Glenn Macnow-

I'm one of those people who couldn't see the hand in front of their face when it's two feet in front. I wore glasses up until my 30's; I wore contacts after that. I hated it. I hated breaking the glasses. I hate cleaning the lenses. I hated not being able to see in the morning until I put the glasses on, I couldn't even read the clock.

When I came to Nevyas Eye Associates what I really liked is, I didn't feel as if they were salespeople and they weren't trying to push me into it. They explained everything that was going to happen, step by step. I must have asked them six thousand questions, they never got tired of my questions. I probably had a lot of stupid questions. They never made me feel stupid about them. They figuratively held my hand through the procedure. I'm still amazed that I go to a football game, I go see the Philadelphia Eagles, and I'm up in the press box, I'm talking 200 yards away on the other side of the field is the head

coach and I can see what he's saying and I can make out who he's talking to and I can see forever and that really has amazed me. I'll tell you something else and this again may sound corny, colors are brighter than they were. I used to see the leaves on the tress, I used to see the distance as sort of a shading of colors. Now I see the leaves on the trees and it's individual leaves. Now I look off into the distance and I can see the color breaking into that color. The surprise was how much better I see. I figured I would see about the same but not have to wear the glasses or the contacts. What I learned is, how much better I could see.

MOJO INTERACTIVE

FAX

To: Dr. Sterling Fax: 609-985-1191

From: Christina Brooks Date: 6/10/99

Re: Web-site Creation Materials Pages: 13 including cover

CC:

O Urgent O For Review O Please Comment O Please Reply O Please Recycle

Comments:

Dr. Richard Sterling.

These are the contracts and forms stating the materials that we need completed before we can start developing the web-site. I did review your file and Dr. Nevyas has not sent back the signed contracts. I did send them again just in case they were misplaced. We have the faxed copy in the file now but we do need the originals. If you have any questions please contact me. Have a great day.

Christina Brooks - they did not

Christina Brooks

Mojo Interactive Corporation

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Nevyas Eye Associates / Delaware Valley Laser Surgery Institute
Ambulatory Surgery Center

FAX COVER SHEET

Herbert J. Nevyas, M.D.
Cataract, Refractive, and Corneal Surgery

Joann Y. Nevyas, M.D.
Cataract & Glaucoma Surgery and Therapy

Anita Nevyas-Wallace, M.D.
Cataract, Refractive, and Corneal Surgery

Ira B. Wallace, M.D.
Ophthalmic Plastic & Reconstructive Surgery

Edward A. Deglin, M.D.
Vitreo-retinal Disease & Surgery

Mitchell E. Stein, M.D.
Glaucoma, Retinal Disease, Medical & Surgical Opthalmology

John M. DeVaro, M.D.
Pediatric Opthalmology, Ocular Motility & Neuro-Opthalmology

Richard H. Sterling, O.D.
Interprofessional Relations Refractive Surgery Coordinator

DATE: 6-29-99

TO: Christina Brooks

COMPANY: Mayo

FAX #: 407-830-9917

FROM: D. Richard Sterling

NAME: Nevyas Eye Assoc.

FAX #: (610)668-1509 BALA CYNWYD, PA

NUMBER OF PAGES INCLUDING THIS ONE: 6

I didn't remember if I had faxed this to you for use in our site. How are "we" progressing Give me an update

admin\fax

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Nevyas Eye Associates / *Delaware Valley Laser Surgery Institute*
Ambulatory Surgery Center

6-10-99

Christina Brooks
Mojo Interactive Corporation

Dear Christina:

I'm faxing you some information for you to get started on our web site design. I'll give you my input and Dr. Nevyas is working on his suggestions as we speak. I'll forward the original signed contracts as well as additional information ASAP. Please feel free to contact me at any time and I'll try and expedite answers or preferences. Thanks in advance for your assistance.

Sincerely,

Richard H. Sterling, OD

Herbert J. Nevyas, M.D.
Refractive, Cataract, and Corneal Surgery

Joann Y. Nevyas, M.D.
Cataract and Glaucoma Surgery and Therapy

Anita Nevyas-Wallace, M.D.
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Ira B. Wallace, M.D.
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Edward A. Deglin, M.D.
Vitreo-retinal Disease and Surgery

Mitchell E. Stein, M.D.
Retinal Disease, Glaucoma Medical and Surgical Ophthalmology

Rick S. Choe, M.D.
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Nevyas Eye Associates- LASIK Results

The refractive surgeons of Nevyas Eye Associates, **Drs. Anita Nevyas-Wallace** and **Herbert Nevyas** pride themselves on their dedication to excellence in all surgeries they perform including laser assisted procedures such as **LASIK**. Since we began doing this technique we tried to do as much as possible to guarantee a quality result. Our dedication and hard work has paid off in the form of many very happy patients.

When excimer laser was first approved for use on the cornea in October 1995 Nevyas Eye Associates began using the excimer beam directly on the third layer of the front part of the eye, cornea (LASIK), to minimize patient postoperative discomfort and complications. Many surgeons began laser technology with PRK which is simply using the excimer to remove the first, second and part of the third layer of the cornea. Because the surgeons of Nevyas Eye Associates had experience with ALK surgery ("lifting a flap") before excimer technology was approved they were able to offer what has now been accepted as the procedure of choice for excimer laser namely LASIK.

The **patients who have had LASIK** for their distance vision (not the monovision eye) and who have at least 180 days followup have attained **20/40 or better unaided** (no glasses or contacts needed) **vision in 94% of the cases.** Of those same patients **80% have 20/25 or better** and **57% have 20/20 or better** unaided visual acuity.

The surgeons of Nevyas Eye Associates have worked very hard to improve the technique as much as possible. In February of 1998 the Drs. Nevyas invented a **fixation device** to minimize decentered laser ablations (when the laser "vaporizes" corneal tissue). The results speak for themselves **97%** of the patients we've done LASIK for are **within +/- 1.50 diopters** (smallest increment is 0.25 diopter) and **71% are within +/- 0.50 diopters.** Although there are very few **overcorrections** (removing all nearsightedness and creating farsightedness) the majority were **less than +0.50 diopters.**

Although the literature states the more myopia (nearsightedness) exists pre surgery the less the predicted result we have found that those patients having LASIK, including those up to 10 diopters of power, have all attained at least 20/40 or better unaided visual acuity in at least 92% of the cases. When selecting out one specific limited parameter **(4-6 diopters) we found 100% of those patients saw 20/40 or better!**

The LASIK procedure seems to be a wonderful procedure for a very large percentage of the cases. This does not mean it is a perfect procedure but you may rest assured that when you choose to have either Dr. Anita Nevyas-Wallace or Dr. Herbert Nevyas perform LASIK on your eyes you will be in very experienced and reliable "hands".

If you should have any questions regarding the procedures that we offer at Nevyas Eye Associates, remaining concerns, or additional statistics please don't hesitate to call us at the Delaware Valley Refractive Surgery Partnership **at 1-800-9-LASER-6.**

FAX FROM: ROANOKE TECHNOLOGY CORP +1-252-537-3125 TO: 816106683553 PAGE: 1 OF 1

Below is the latest "Visibility Report" for your web site http://www.lasercosmeticsurgery.net.
It shows your rankings on the major search engines for the term construction.
If you need a new report you may request one at our site: www.top-10.com.
If you or your company need better visibility in the search engines you may contact us directly at: +1-252-537-9222 option 1.

Date: 9/20/2000

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0 -- Snap!
NR -- PC Beacon
0 -- MSN Search
0 -- Open Directory Project
0 -- Excite
0 -- AltaVista
0 -- Netscape NetFind
0 -- AOL Search
0 -- HotBot
0 -- Web Crawler
0 -- DirectHit
0 -- Yahoo!
0 -- Northern Light
0 -- AllTheWeb
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Roanoke Rapids, NC 27870 USA
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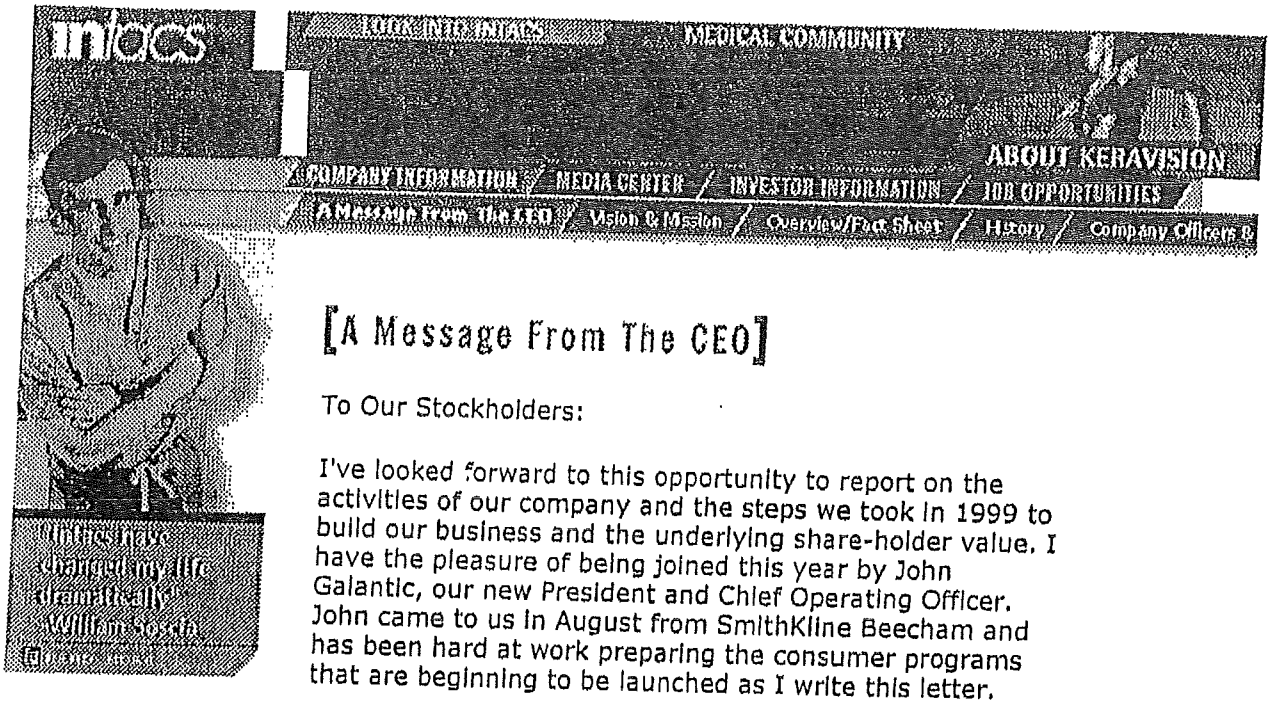


[A Message From The CEO]

To Our Stockholders:

I've looked forward to this opportunity to report on the activities of our company and the steps we took in 1999 to build our business and the underlying share-holder value. I have the pleasure of being joined this year by John Galantic, our new President and Chief Operating Officer. John came to us in August from SmithKline Beecham and has been hard at work preparing the consumer programs that are beginning to be launched as I write this letter.

The theme for this year's annual report is the personal stories behind Intacs. We chose the look of a well known human-interest magazine because Intacs are such a human-interest story. Our product can change millions of lives for the better. It was in recognition of this that Intacs were recently named by CNN and Health magazine to their joint list of "The Year's Top 10 Medical Advances." (More about that later.)

Now, let me tell you about the major projects and achievements that made 1999 a pivotal year in the transition from a research and development organization to a consumer-driven company.

1999:The end of the "beginning"

The research phase of the company, which is the foundation on which KeraVision was built, achieved its primary objective in April 1999 when we received Food and Drug Administration approval to sell Intacs prescription inserts for correcting mild myopia, or nearsightedness. This followed eight years of clinical studies proving that Intacs are a safe, effective treatment for a condition that affects an estimated 20 million American consumers. Along the way, we acquired 29 U.S. patents, 59 foreign patents and another 168 pending.

Throughout the rest of 1999, the company's total focus was on commercial development. Phase 1 was medical market development - that is, preparing surgeons and their staffs to receive Intacs consumers. We started by training

surgeons to achieve excellent clinical results for their Intacs clients. Where we originally set 200 doctors as the training goal for 1999, surgeon demand pushed the actual number past 600.

In the months following FDA approval, over 2,300 Intacs procedures were performed. The effectiveness of the surgeon training program can be demonstrated by the fact that, in these initial cases, results appear in line with the excellent results achieved during the Intacs clinical trials. That means 20/20 vision or better, minimal discomfort and rapid visual recovery in most cases.

Once surgeons were trained, we switched gears in the fourth quarter and focused on training surgeons staffs. We want every employee in each surgeon's practice to able to fully communicate the unique attributes of Intacs to their clients and to fully manage the client's experience. Each step of the transaction is covered in this training, from answering clients' basic questions about Intacs, to conducting formal clinical consultations, to supporting the surgeon in the Intacs procedure, to providing postoperative care. The goal is to leave nothing to chance when it comes to meeting the expectations of the Intacs consumer.

A foundation of "Fast Track" practices

As I write to you, we are conducting practice-development training with about 40 surgeons' practices, and additional practices are scheduled to undergo training every quarter. We refer to this group as "Fast Track" practices because of their commitment to making Intacs the procedure of choice for mildly near-sighted clients. (By "mildly" nearsighted, we mean people with vision of between 20/40 and 20/400 who need glasses or contacts for tasks like driving, watching a movie, or seeing an alarm clock in the morning.)

We, in turn, make a commitment to the Fast Track practices that we will help insure their clinical and commercial success by supporting them with marketing programs ranging from cooperative advertising, to special promotions, to strategies designed to help expand referral channels between Fast Track surgeons and referring optometrists. Mid-year, expect to see us roll out a new direct-to-consumer, interactive Internet site. When you consider our consumer profile—high education, high income, high Internet use—the Internet seems to make a great deal of sense.

The Fast Track practices form the foundation for receiving Intacs consumers.

Using what we've learned about the consumer. People have asked me why we didn't initiate these direct-to-

consumer programs earlier. The fact is, until the surgeon and total practice infrastructure was in place and ready to receive consumers, it would have been irresponsible to spend money on consumer marketing. Moving through the year 2000, we intend to link consumers with Fast Track practices through marketing programs that we believe will build KeraVision's business by building the Fast Track practices' business.

In developing these marketing programs, the company made a significant investment in 1999 in learning more about our consumers and the decision process for giving up eyeglasses and contact lenses in exchange for Intacs. We applied these learnings in developing Fast Track marketing models aimed at creating consumer demand. During the first half of 2000, one of our jobs will be to test and fine-tune these models. Because of the research work, we feel confident in our grasp of Intacs consumers - who they are, where to find them, and what needs to happen to make them satisfied Intacs wearers who will want to help convert family and friends to becoming Intacs consumers.

Intacs: One of "The Year's Top 10 Medical Advances"
We finished 1999 with Intacs being chosen one of "The Year's Top 10 Medical Advances" by CNN and its partner, Health magazine. In their joint report, Intacs were recognized for attributes that we believe make Intacs unique and appealing to many people with mild nearsightedness. In their words, Intacs belong to the year's list of "best discoveries" because Intacs are:

- "relatively painless"
- "take only a few minutes"
- "leave the eyes unaltered"
- "if the results aren't up to par or a recipients' vision changes later, the implants can be removed or replaced",
- "less frightening treatment for the myopic millions",

The real honor of this recognition goes to the R&D and clinical group, including those from the earliest days such as Darlene Crockett-Billig, Tom Silvestrini, John Scholl, Val Defiesta-Ng and Diana Lopez. Thanks to all who have labored more than a decade to make Intacs a life-improving product worldwide.

Expanding our vision with potential new applications and products

There were a number of initiatives in 1999 that have the potential to lead to new applications for Intacs, including as a complimentary procedure to LASIK. Some surgeons independently began using Intacs prescription inserts in combination with LASIK to treat presbyopia (i.e., the need

for reading glasses) and people who are in the pre-presbyopia stage. With Intacs in at least one eye, consumers enjoy the flexibility for prescription changes that can be necessary as part of the normal aging process.

In Europe, the Company initiated a multi-center clinical study of Intacs in the treatment of keratoconus, a thinning-of-the-cornea disorder that has eluded effective treatments. Also outside the U.S., several surgeons are conducting independent studies of Intacs to treat LASIK induced ectasia that has been observed in some LASIK patients who experience corneal thinning, according to medical literature.

Other surgeons, also acting independently, are using Intacs in combination with LASIK to treat high myopes. In these cases, LASIK is used to bring clients within the Intacs range, at which point Intacs are inserted for final correction. Some surgeons feel this combination procedure gives clients who are normally outside the Intacs range an added margin of safety against LASIK-induced corneal thinning.

Meanwhile, we launched a multi-center hyperopia (farsightedness) study in Europe in 1999. In the U.S., the FDA approved expanding our U.S. Phase III clinical trials of Intacs for wider ranges of myopia than are currently approved for sale. Both the hyperopia and myopia studies are progressing on schedule.

As our technology continues to evolve, KeraVision is providing surgeons with unique new practice-building opportunities and consumers with safe and convenient new vision correction options. Increasingly, Intacs are a solution that's hard to ignore. I look forward to keeping you informed as we achieve results with our marketing programs and expand our market with potential new applications for Intacs.

Best personal regards,

Thomas M. Loarie
Chairman and Chief Executive Officer

back to top

Crystalens Intraocular Lens

Nevyas Eye Associates is proud to be the first in the Delaware Valley to be certified to perform the Crystalens IOL surgery.

Why Crystalens?

The answer is simple. Crystalens offers patients the chance to see the way they want to see, without the help of glasses or contact lenses.... near, far and all distances in between, effortlessly. Everyday tasks, such as reading the morning paper, watching your children play baseball, or just driving to work are once again a possibility, usually without depending on glasses or contacts. Why Crystalens? Why not?

What is Crystalens?

Crystalens is a revolutionary breakthrough in refractive and cataract surgeries. It is the first and only intraocular lens that allows patients to focus at all distances, much like their own natural lens once did. This lens works with the muscles of the eye to restore vision at near, far and everywhere in between. It is designed to move when the patient attempts to see at different distances. This movement is what gives the Crystalens its unique focusing ability. Crystalens can be used to replace a natural lens that has developed a cataract, as well as a natural lens that does not have a cataract. When there is not a cataract present, the surgery would be considered elective, and be done in order to eliminate the need for glasses and contacts.

How does Crystalens work?

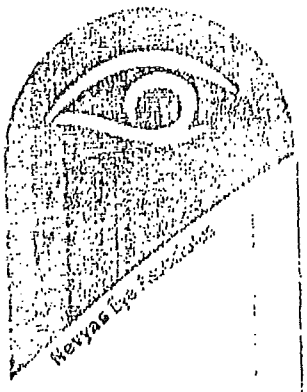
The Crystalens is designed with two hinges that allow the lens to move back and forth as the muscles in the eye contract and relax. This movement is what gives patients the ability to see at all distances seamlessly. Most patients are able to see without depending on glasses for near or far soon after surgery.

The Crystalens is implanted in the same, safe manner that traditional intraocular lenses have been for over 30 years. Our surgeons use a small incision to first remove the patient's current lens, and then implant the Crystalens in its place. Follow up and post-operative care is very similar to that of traditional cataract or refractive lensectomy patients.

Who are the best Crystalens candidates?

Crystalens is well suited for men and women who are between the ages of 40-65, who are either bothered by cataracts or just bothered by nearsightedness, farsightedness or presbyopia. It is ideal for patients who not only want to restore vision lost due to cataracts or aging, but who also want to greatly reduce their dependency on glasses and contacts. We are proud to have Crystalens as an alternative for those patients who are not candidates for LASIK.

A complete eye exam by one of our surgeons is necessary to determine if Crystalens is truly the best option. To schedule an exam, please call 800-952-7376, or fill out the information under contact us.(LINK)



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Other Practices of Nevyas Eye Associates
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Nevyas Eye Associates

▶ Anita Nevyas-Wallace, M.D. ▶ Herbert J. Nevyas, M.D. ▶ Joann Yaskin Nevyas, M.D. ▶ Ira B. Wallace, M.D. ▶ Edward A. Deglin, M.D. ▶ Mitchell E. Stein, M.D. ▶ Joseph M. Ortiz, M.D. ▶ Richard Sterling, O.D.

Herbert J. Nevyas, M.D.

Dr. Herbert J. Nevyas is a recognized leader in ophthalmic surgery, particularly cataract and refractive surgery. He is a Clinical Professor of Surgery in Ophthalmology at the Allegheny University Hospitals-MCP Division. He received his undergraduate and medical degrees from the University of Pennsylvania, where he was awarded the Oliver Memorial Prize in Ophthalmology. He completed his postgraduate training at Thomas Jefferson University, the Institute of Ophthalmology of the University of London and the Hospital of the University of Pennsylvania.

Dr. Nevyas has operated a practice in medical and surgical ophthalmology since 1964. Nevyas Eye Associates currently has four locations: Bala Cynwyd, Center City Philadelphia, Northeast Philadelphia and Marlton, New Jersey. He founded the practice's ambulatory surgical center, the Delaware Valley Laser Surgery Institute in 1989.

An innovator in surgical equipment and procedures, Dr. Nevyas holds a number of ophthalmic patents. Techniques and instruments bearing his name are used worldwide. He also has invented two varieties of intraocular lens implants. In addition to cataract and a full range of refractive surgery procedures including LASIK excimer laser surgery, Dr. Nevyas performs other procedures including corneal transplant and YAG laser surgery. He has lectured widely and has authored more than 40 ophthalmic publications.

NYA 00785

Dr. Nevyas is a Diplomate of the American Board of Ophthalmology, a Fellow of the American Academy of

Ophthalmology, a founding member of the American Society for Cataract and Refractive Surgery, and a member of numerous other professional organizations.

▸ Next

Nevyas Eye Associates

1.800.9LASER.6

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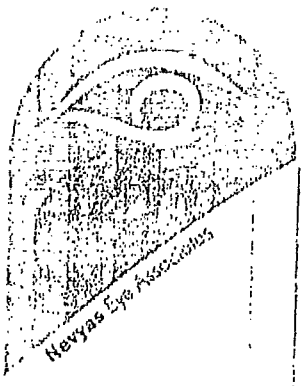

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Nevyas Eye Associates

▸ Anita Nevyas-Wallace, M.D. ▸ Herbert J. Nevyas, M.D. ▸ Joann Yaskin Nevyas, M.D. ▸ Ira B. Wallace, M.D. ▸ Edward A. Deglin, M.D. ▸ Mitchell E. Stein, M.D. ▸ Joseph M. Ortiz, M.D. ▸ Richard Sterling, O.D.

Joann Yaskin Nevyas, M.D.

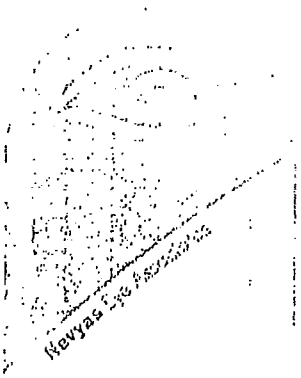
Dr. Joann Yaskin Nevyas has practiced ophthalmology since 1973, with a special interest in laser and medical treatment of glaucoma. She is a Clinical Associate Professor of Surgery at the Allegheny University Hospitals-MCP Division, and practices at Nevyas Eye Associates.

Dr. Nevyas earned her undergraduate degree from the University of Pennsylvania and her medical degree from the Medical College of Pennsylvania. She completed a preceptorship in ophthalmology under Dr. Herbert J. Nevyas. This program, approved by the American Board of Ophthalmology, also included training at the Schele Eye Institute, Wills Eye Hospital and Children's Hospital of Philadelphia.

A Diplomate of the American Board of Ophthalmology and a Fellow of the American Academy of Ophthalmology, Dr. Nevyas is an active member of many ophthalmic societies. She has had extensive experience in combined cataract-glaucoma surgery, a topic on which she has lectured and written. Dr. Nevyas received the "Best Paper of Session" award at the 1995 American Society of Cataract and Refractive Surgeons meeting for her work on combined cataract and glaucoma surgery.

▸ Next

Nevyas Eye Associates



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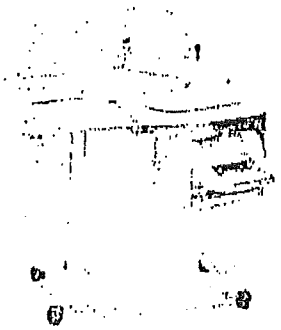
LADARwave Custom Cornea

We have upgraded our LADARvision system to include the brand new LADARwave Custom Cornea system. It is now possible to provide a truly customized treatment for all of our LASIK patients. **Drs. Anita Nevyas-Wallace and Herbert Nevyas are proud to be the very first surgeons in the Philadelphia area to offer this new technology.**

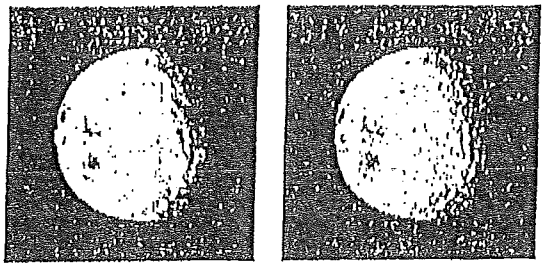
LADARwave represents a breakthrough in laser vision correction and can provide results that are even better than conventional laser treatments! It is the only FDA-approved wavefront technology available, and will certainly become the future of laser vision correction.



LADARwave uses the Custom Cornea system to measure "aberrations", or distortions in your eye's optical system. Before LADARwave, lasers were only able to treat the lower levels of distortion, those being nearsightedness, farsightedness and astigmatism. While these distortions account for 85-90% of the quality of your vision, the remaining 10-15% was left unaddressed. Now, with the LADARwave system we can finally address and treat these remaining higher levels of distortion.

We have learned that the other, higher-level distortions that can cause a decrease in the clarity of your vision. They can affect your vision both at night and in low light. They would present themselves in the way of glare, halos and shadows. Every patient has some level of both higher and lower level distortion, so every patient has the potential to see better with the LADARwave treatment.

NYA 00807



Before Enhancement After Enhancement

Taking the eye chart as an example, just being able to see the 20/20 line doesn't always mean that your vision is ideal. The eye chart can only measure how small an image you can see, not how clearly you see those images. Higher-level distortions can cause even the 20/20 line to become shadowed or to have a "double image". Just being able to identify the letters on the chart doesn't always mean that you have excellent vision. By treating these higher-level distortions, the quality of your vision can be significantly improved.

Before Enhancement 20/20

The goal of LADARwave Custom Cornea treatments is to address the remaining 10-15% of higher-level distortions in the eye. By doing this, your surgeon can decrease the risk of undesirable side effects and improve both the quality of your vision and of your way of life. Custom Cornea is able to achieve this goal by mapping each patient's individual optical distortions and then translate those distortions to the LADARvision system to help guide the laser as it reshapes your cornea.

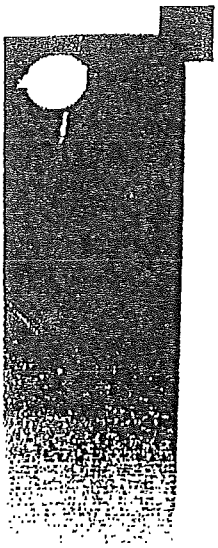
To find out if LADARwave Custom Cornea is right for you, please call the office to schedule your cost free examinations with one of our surgeons. You can reach us by calling 800-9LASER6 or by clicking here.

NYA 00008

CK (Conductive Keratoplasty)

CK is a relatively new procedure used to treat mildly farsighted

Clinical Research Consultants, Inc.
3307 Clifton Avenue • Cincinnati, Ohio 45220
PH: (513)-961-8200 • FAX: (513)-961-2858
E-Mail: BSFANT@aol.com



January 5, 2002

Everett Beers, Ph.D.
IDE Document Mail Center (HFZ-401)
Center for Devices and Radiological Health
Food and Drug Administration
9200 Corporate Boulevard
Rockville, Maryland 20850

RE: IDE #G970088 Supplement #24 (Nevyas Excimer Laser)

Dear Dr. Beers:

Enclosed in triplicate is IDE Supplement #24 for the above referenced IDE, which I am submitting on behalf of Dr. Herbert Nevyas. This supplement provides the 2001 annual report for this IDE. An interim clinical summary is provided in the report, including an analysis from the contrast sensitivity substudy.

If you have any questions in this regard, please do not hesitate to contact me at (513)-961-8200 or Dr. Nevyas.

Yours Truly,
Barbara Fant
Barbara S. Fant, Pharm.D.
(Consultant to Dr. Herbert Nevyas)

NYA 00872

IDE Supplement No. 24

ANNUAL REPORT

IDE NUMBER:	G970088
DEVICE:	Nevyas Excimer Laser
INVESTIGATOR/ SPONSER:	Herbert J. Nevyas, M.D. * Anita Nevyas-Wallace. M.D. Delaware Valley Laser Surgery Institute 333 City Line Avenue Bala Cynwyd, Pennsylvania 19004 Telephone: (610) 668-2777 FAX: (610) 668-1509
INDICATIONS:	LASIK for Myopia with or without Astigmatism (-0.5 to -22 Diopters Sphere with up to –7 Diopters Astigmatism)
DATE SUBMITTED:	December 30, 2001
PURPOSE:	Supplement #24 is being filed as the annual report.

* Address correspondence to Herbert J. Nevyas, M.D.

ANNUAL REPORT

1.0 STUDY PROGRESS

Since the last annual report (submitted 14 March 2001), monitoring visits have been completed to completely review the data in the database for all subjects through August 1, 2001. The data review showed a very low rate of data entry errors and data in the database were in agreement with the source documents. Data from visits after this date have been reviewed for obvious errors and omissions. The last date of surgery included in this report is December 19, 2001. Dr. Nevyas recently acquired a commercially approved excimer laser and is evaluating whether to continue use of the Nevyas Excimer Laser. Individual summaries of the study progress for NEV-97-001 and Substudy NEV-98-002 are provided below. An interim clinical summary for NEV-97-001 and NEV-98-002 (contrast sensitivity) is attached to the end of this submission.

1.1 PROTOCOL NEV-97-001 – LASIK for Myopia with or without Astigmatism (-0.5 D to –22.00 D sphere; 0 to –7.0 D cylinder)

A. STATUS: Ongoing

B. NUMBER OF INVESTIGATORS: Two

This remains a single site study which is being conducted by the joint sponsor-investigators:

Herbert J. Nevyas, M.D.
Anita Nevyas-Wallace, M.D.
Delaware Valley Laser Surgery Institute
333 City Line Avenue
Bala Cynwyd, Pennsylvania 19004
Telephone: (610) 668-2777
Fax: (610) 668-1509

C. NUMBER OF SUBJECTS ENROLLED:

1.	Number of Subjects Enrolled:	779 IDE Subjects Total
	Number of Eyes Treated:	779 Primary eye treatments
		714 Fellow eye treatments
		1,493 Total eyes treated
2.	First Date of Enrollment:	August 28, 1997
	Last Date of Enrollment:	December 19, 2001

D. NUMBER OF DEVICES SHIPPED:

Not Applicable. The device was assembled on-site at Nevyas Eye Center. No additional devices have been shipped or assembled.

E. SUMMARY OF CLINICAL RESULTS

An interim clinical summary is provided in Attachment 1.1.E-1. The clinical summary includes the following tables:

- Accountability
- Preoperative Refractive Parameters *(eyes treated for sphere only)*
- Summary of Key Safety and Efficacy Variables
- Comparison with FDA Safety and Effectiveness Criteria
- Stability of Manifest Refraction
- Number of Eyes within the Preop Sphere and Cylinder Range *(myopic astigmatism eyes only)*
- Accuracy of Sphere (to target) and Cylinder to Zero Component *(myopic astigmatism eyes only)*
- Residual Astigmatic Error at Stability Time Point *(myopic astigmatism eyes only)*
- Vector Analysis Summary Tables
- Safety Summary Tables (adverse events, complications, subjective complaints)
- Contrast Sensitivity Analysis

G. SUMMARY OF COMPLICATIONS AND ADVERSE EVENTS:

The complications and adverse events that occurred intraoperatively and postoperatively for the 1,493 eyes treated under the IDE are summarized in the clinical summary in Attachment 1.1.E-1.

1.2 Substudy NEV-97-002: Changes in Contrast Sensitivity in Patients Undergoing LASIK Treatment with the Nevyas Excimer Laser

A. Substudy to Protocol: NEV-97-001 (Myopia/Myopic Astigmatism)

B. STATUS: Complete

C: NUMBER OF INVESTIGATORS: Two

This remains a single site study which is being conducted by the joint sponsor-investigators:

Herbert J. Nevyas, M.D.
Anita Nevyas-Wallace, M.D.
Delaware Valley Laser Surgery Institute
333 City Line Avenue
Bala Cynwyd, Pennsylvania 19004
Telephone: (610) 668-2777
Fax: (610) 668-1509

D. NUMBER OF SUBJECTS ENROLLED:

1. Number of Subjects Enrolled: 92 Low myopia subjects
21 High myopia subjects
Total of 184 eyes tested

E. SUMMARY OF RESULTS

A summary of the contrast sensitivity testing results is included in the interim clinical summary provided in Attachment 1.1.E-1.

2.0 RISK ANALYSIS

The risk analysis remains unchanged from that submitted with the original IDE. There are no emerging complications or adverse events that alter the risk analysis. The adverse event and complication rates remain low.

3.0 DEVICE CHANGES

No device changes have occurred since the last annual report.

4.0 CHANGES IN INVESTIGATIONAL PLAN

All reportable changes to the investigational plan have been previously submitted to the FDA for review and approval via amendments, revised versions of the protocol(s), or substudies.

5.0 PROGRESS TOWARDS PMA APPROVAL

All preoperative and postoperative data obtained through August 1, 2001 have been monitored and compared to the source documents. Any reportable adverse events, complications, or subjective complaints noted in the source documents were added to the study database. Preparation of this interim report has generated some additional data entry queries that are outstanding. A comprehensive software validation was completed and a quality system for maintenance and replacement of device components is in process.

Dr. Nevyas has obtained a commercially available excimer laser for use in his practice and is currently evaluating the results compared to the Nevyas Excimer Laser to determine whether to pursue filing the PMA for Nevyas Excimer Laser. If he decides to pursue the PMA approval, work on preparation of the PMA will begin the end of January 2002 with filing expected by the end of February 2002.

MAY 12 2003

Schulman Associates IRB
Institutional Review Board, Inc.
John M. Isidor, J.D., CEO

VIA CERTIFIED MAIL

May 8, 2003

Herbert J. Nevyas, M.D.
Nevyas Eye Associates
333 E. City Line Ave., Suite 2
Bala Plaza
Bala Cynwyd, PA 19004

SUBJECT: Request for Information to Complete Interim Report Form
SPONSOR: Nevyas Eye Associates
PROTOCOL NO: NEV-97-001

To date the Board has not received a satisfactory response from your site regarding items for submission or clarification, in order to process your interim report form. Attempts to contact your site were made via facsimile on 2/17, via facsimile and telephone on 3/21, via facsimile on 4/16, via telephone on 4/17, and via telephone to your monitor, Barbara Fant, on 4/25 and 5/2. Dr. Sterling left me voicemails on Monday 4/28 and Wednesday 5/7/03 indicating his intentions to follow up on this issue. However, I did not receive the requested document. The outstanding issue is described below.

Therefore, please respond to the following request:

- Please submit a signed copy of the Contrast Sensitivity Substudy informed consent form, dated 5/28/1998, signed by the last subject to sign this form.

Please submit your detailed written response, signed by Dr. Nevyas, within five (5) business days of receipt of this letter. You may fax your response to Kevin Zemko at (513) 761-1154. If questions, please call (513) 761-4100, ext. 149.

Your failure to comply may negatively impact the Board's consideration of your future submissions.

Sincerely,

Kevin R Zemko

Kevin R. Zemko, BA, BS
Administrative Assistant, Regulatory Affairs

cc: Barbara Fant, Clinical Research Consultants, Inc.

PLEASE USE OUR IRB # 97-1942-0 ON ALL CORRESPONDENCE FOR THIS STUDY

NYA 00922

4290 Glendale-Milford Road Cincinnati, Ohio 45242 Phone: (513) 761-4100 Fax (513) 761-5546

code of federal regulations

Food and Drugs

21

PARTS 800 TO 1299

Revised as of April 1, 1994

CONTAINING
A CODIFICATION OF DOCUMENTS
OF GENERAL APPLICABILITY
AND FUTURE EFFECT

AS OF APRIL 1, 1994

With Ancillaries

Published by
the Office of the Federal Register
National Archives and Records
Administration

as a Special Edition of
the Federal Register

The contents of the historical file
be physically located in more than
place in the establishment or in
than one establishment provided
exists joint ownership and con-
among all the establishments
taining the historical file. If no
ownership and control exists, the
tered establishment must provide
Food and Drug Administration
a letter authorizing the establish-
outside its control to maintain
istorical file.

Each owner or operator shall be
ired to submit to the Food and
Administration, only upon spe-
request, the following informa-

For a device subject to section 514
5 of the act that is not a restricted
ce, a copy of all labeling for the de-

For a device that is a restricted
ce, a copy of all labeling for the de-
a representative sampling of ad-
isements for the device, and for
cause, a copy of all advertise-
ts for a particular device. A re-
t for all advertisements will, where
ible, be accompanied by an explan-
on of the basis for such request.

) For a device that is neither a re-
cted device, nor subject to section
of 515 of the act, the label and pack-
insert for the device and a rep-
ntative sampling of any other la-
ng for the device.

) For a particular device, a state-
t of the basis upon which the reg-
ant has determined that the device
ot subject to section 514 or 515 of
act.

) For a particular device, a state-
t of the basis upon which the reg-
ant has determined the device is
a restricted device.

) For a particular device, a state-
t of the basis for determining that
product is a device rather than a
g.

) For a device that the owner or op-
tor has manufactured for distribu-
n under a label other than its own,
names of all distributors for whom
has been manufactured.

FR 37999, Aug. 25, 1978, as amended at 51
31631, Sept. 18, 1986]

§ 807.35 Notification of registrant.

(a) The Commissioner will provide to the official correspondent, at the address listed on the form, a validated copy of Form FD-2891 or Form FD-2891(a) (whichever is applicable) as evidence of registration. A permanent registration number will be assigned to each device establishment registered in accordance with these regulations.

(b) Owners and operators of device establishments who also manufacture or process blood or drug products at the same establishment shall also register with the Center for Biologics Evaluation and Research and Center for Drug Evaluation and Research, as appropriate. Blood products shall be listed with the Center for Biologics Evaluation and Research, Food and Drug Administration, pursuant to Part 607 of this chapter; drug products shall be listed with the Center for Drug Evaluation and Research, Food and Drug Administration, pursuant to Part 207 of this chapter.

(c) Although establishment registration and device listing are required to engage in the device activities described in § 807.20, validation of registration and the assignment of a device listing number in itself does not establish that the holder of the registration is legally qualified to deal in such devices and does not represent a determination by the Food and Drug Administration as to the status of any device.

[42 FR 42528, Aug. 23, 1977, as amended at 43 FR 37999, Aug. 25, 1978; 53 FR 11252, Apr. 6, 1988]

§ 807.37 Inspection of establishment registration and device listings.

(a) A copy of the forms FD-2891 and FD-2891a filed by the registrant will be available for inspection in accordance with section 510(f) of the act, at the Center for Devices and Radiological Health (HFZ-342), Food and Drug Administration, Department of Health and Human Services, 1390 Piccard Dr., Rockville, MD 20850. In addition, there will be available for inspection at each of the Food and Drug Administration district offices the same information for firms within the geographical area of such district office. Upon request, verification of registration number or

location of a registered establishment will be provided.

(b)(1) The following information filed under the device listing requirements will be available for public disclosure:

(i) Each form FD-2892 submitted;

(ii) All labels submitted;

(iii) All labeling submitted;

(iv) All advertisements submitted;

(v) All data or information that has already become a matter of public knowledge.

(2) Requests for device listing information identified in paragraph (b)(1) of this section should be directed to the Center for Devices and Radiological Health (HFZ-342), Food and Drug Administration, Department of Health and Human Services, 1390 Piccard Dr., Rockville, MD 20850.

(3) Requests for device listing information not identified in paragraph (b)(1) of this section shall be submitted and handled in accordance with Part 20 of this chapter.

[43 FR 37999, Aug. 25, 1978, as amended at 53 FR 11252, Apr. 6, 1988; 55 FR 11169, Mar. 27, 1990]

§ 807.39 Misbranding by reference to establishment registration or to registration number.

Registration of a device establishment or assignment of a registration number does not in any way denote approval of the establishment or its products. Any representation that creates an impression of official approval because of registration or possession of a registration number is misleading and constitutes misbranding.

Subpart C—Registration Procedures for Foreign Device Establishments

§ 807.40 Establishment registration and device listing for foreign manufacturers of devices.

(a) Foreign device establishments that export devices into the United States are requested to register in accordance with the procedures of subpart B of this part, unless exempt under subpart D of this part.

(b) Foreign device establishments that export devices into the United States, whether or not the establishment is registered, shall comply with the device listing requirements unless exempt from registration as stated in § 807.65. Those foreign owners or operators for which there exists joint ownership and control with a domestic establishment may have the domestic establishment submit listing information and maintain the historical file. A foreign owner or operator may authorize a domestic initial distributor to submit listing information when joint ownership and control does not exist, only if:

(1) The domestic distributor is the sole initial distributor for the foreign owner or operator's device; and

(2) The foreign owner or operator submits a letter to the Food and Drug Administration authorizing the initial distributor to list on its behalf and maintain the historical file.

(c) Except for a device imported or offered for import that has in effect an approved exemption for investigational use under section 520(g) of the act, a device may not be imported from a foreign device establishment into the United States unless it is listed at the interval specified for updating device listing information in § 807.30(b). The device listing information shall be in the English language.

(d) Foreign device establishments shall submit, as part of the device listing, the name and address of the establishment and the name of the individual responsible for submitting device listing information. Any changes in this information shall be reported to the Food and Drug Administration at the intervals specified for updating device listing information in § 807.30(b).

[43 FR 37999, Aug. 25, 1978]

Subpart D—Exemptions

§ 807.65 Exemptions for device establishments.

The following classes of persons are exempt from registration in accordance with § 807.20 under the provisions of section 510(g) (1), (2), and (3) of the act, or because the Commissioner has found, under section 510(g)(4) of the act, that such registration is not necessary for the protection of the public health:

(a) A manufacturer of raw materials or components to be used in the manufacture or assembly of a device who

ld otherwise not be required to reg- r under the provisions of this part.
) A manufacturer of devices to be d solely for veterinary purposes.
) A manufacturer of general pur- e articles such as chemical reagents laboratory equipment whose uses generally known by persons trained their use and which are not labeled promoted for medical uses.
d) Licensed practitioners, including ysicians, dentists, and optometrists, o manufacture or otherwise alter de- ces solely for use in their practice.
(e) Pharmacies, surgical supply out- ts, or other similar retail establish- ents making final delivery or sale to e ultimate user. This exemption also pplies to a pharmacy or other similar etail establishment that purchases a evice for subsequent distribution nder its own name, e.g., a properly la- eled health aid such as an elastic ban- age or crutch, indicating "distributed y" or "manufactured for" followed by he name of the pharmacy.

(f) Persons who manufacture, pre- pare, propagate, compound, or process devices solely for use in research, teaching, or analysis and do not intro- duce such devices into commercial dis- tribution.

(g) [Reserved]

(h) Carriers by reason of their re- ceipt, carriage, holding or delivery of devices in the usual course of business as carriers.

(i) Persons who dispense devices to the ultimate consumer or whose major responsibility is to render a service necessary to provide the consumer (i.e., patient, physician, layman, etc.) with a device or the benefits to be derived from the use of a device; for example, a hearing aid dispenser, optician, clinical laboratory, assembler of diagnostic x- ray systems, and personnel from a hos- pital, clinic, dental laboratory, orthotic or prosthetic retail facility, whose primary responsibility to the ul- timate consumer is to dispense or pro- vide a service through the use of a pre- viously manufactured device.

[42 FR 42526, Aug. 23, 1977, as amended at 58 FR 46523, Sept. 1, 1993]

Subpart E—Premarket Notification Procedures

§ 807.81 When a premarket notification submission is required.

(a) Except as provided in paragraph (b) of this section, each person who is required to register his establishment pursuant to § 807.20 must submit a pre- market notification submission to the Food and Drug Administration at least 90 days before he proposes to begin the introduction or delivery for introduc- tion into interstate commerce for com- mercial distribution of a device in- tended for human use which meets any of the following criteria:

(1) The device is being introduced into commercial distribution for the first time; that is, the device is not of the same type as, or is not substan- tially equivalent to, (i) a device in commercial distribution before May 28, 1976, or (ii) a device introduced for commercial distribution after May 28, 1976, that has subsequently been reclas- sified into class I or II.

(2) The device is being introduced into commercial distribution for the first time by a person required to reg- ister, whether or not the device meets the criteria in paragraph (a)(1) of this section.

(3) The device is one that the person currently has in commercial distribu- tion or is reintroducing into commer- cial distribution, but that is about to be significantly changed or modified in design, components, method of manu- facture, or intended use. The following constitute significant changes or modi- fications that require a premarket no- tification:

(i) A change or modification in the device that could significantly affect the safety or effectiveness of the de- vice, e.g., a significant change or modi- fication in design, material, chemical composition, energy source, or manu- facturing process.

(ii) A major change or modification in the intended use of the device.

(b) A premarket notification under this subpart is not required for a device for which a premarket approval appli- cation under section 515 of the act, or for which a petition to reclassify under section 513(f)(2) of the act, is pending

before the Food and Drug Administra- tion.

(c) In addition to complying with the requirements of this part, owners or operators of device establishments that manufacture radiation-emitting elec- tronic products, as defined in § 1000.3 of this chapter, shall comply with the re- porting requirements of Part 1002 of this chapter.

§ 807.85 Exemption from premarket notification.

(a) A device is exempt from the pre- market notification requirements of this subpart if the device intended for introduction into commercial distribu- tion is not generally available in fin- ished form for purchase and is not of- fered through labeling or advertising by the manufacturer, importer, or dis- tributor thereof for commercial dis- tribution, and the device meets one of the following conditions:

(1) It is intended for use by a patient named in the order of the physician or dentist (or other specially qualified person); or

(2) It is intended solely for use by a physician or dentist (or other specially qualified person) and is not generally available to, or generally used by, other physicians or dentists (or other specially qualified persons).

(b) A distributor who places a device into commercial distribution for the first time under his own name and a repackager who places his own name on a device and does not change any other labeling or otherwise affect the device shall be exempted from the pre- market notification requirements of this subpart if:

(1) The device was in commercial dis- tribution before May 28, 1976; or

(2) A premarket notification submis- sion was filed by another person.

§ 807.87 Information required in a pre- market notification submission.

Each premarket notification submis- sion shall contain the following infor- mation:

(a) The device name, including both the trade or proprietary name and the common or usual name or classifica- tion name of the device.

(b) The establishment registration number, if applicable, of the owner or operator submitting the premarket notification submission.

(c) The class in which the device has been put under section 513 of the act and, if known, its appropriate panel; or, if the owner or operator determines that the device has not been classified under such section, a statement of that determination and the basis for the person's determination that the device is not so classified.

(d) Action taken by the person re- quired to register to comply with the requirements of the act under section 514 for performance standards.

(e) Proposed labels, labeling, and ad- vertisements sufficient to describe the device, its intended use, and the direc- tions for its use. Where applicable, pho- tographs or engineering drawings should be supplied.

(f) A statement indicating the device is similar to and/or different from other products of comparable type in commercial distribution, accompanied by data to support the statement. This information may include an identifica- tion of similar products, materials, de- sign considerations, energy expected to be used or delivered by the device, and a description of the operational prin- ciples of the device.

(g) Where a person required to reg- ister intends to introduce into com- mercial distribution a device that has undergone a significant change or modification that could significantly affect the safety or effectiveness of the device, or the device is to be marketed for a new or different indication for use, the premarket notification sub- mission must include appropriate sup- porting data to show that the manufac- turer has considered what con- sequences and effects the change or modification or new use might have on the safety and effectiveness of the de- vice.

(h) Any additional information re- garding the device requested by the Commissioner that is necessary for the Commissioner to make a finding as to whether or not the device is substan- tially equivalent to a device in com- mercial distribution. A request for ad- ditional information will advise the owner or operator that there is insuffi- cient information contained in the original premarket notification sub-

Clinical Research Consultants, Inc.
3928 North Cliff Lane • Cincinnati, Ohio 45220
Telephone: (513) 751-3637 • FAX: (513)-751-3773

April 10, 1997

Herbert Nevyas, M.D.
Richard Sterling, O.D.
Nevyas Eye Associates
Delaware Valley Laser Surgery Institute
333 East City Line Avenue
Bala Cynwyd, Pennsylvania 19004

RE: Nevyas Excimer Laser IDE

Dear Drs. Nevyas and Sterling:

Your IDE for the Nevyas Excimer Laser was sent to the FDA on Monday, April 7th and should have arrived on Tuesday, April 8th. You will probably receive a letter from the FDA in about a week confirming that it has been received and is under review. The FDA has 30 days from the time of its receipt to review the IDE. Typically, the review letters have been coming out on the 30th day. It then takes another 7 to 10 days for the review letter to reach you.

Please fax a copy of the review letter to Arthur Jackson and myself as soon as you receive it. DO NOT attempt to answer any questions or respond to any of the issues. We will work with you to prepare any necessary response. We expect to receive a conditional approval, meaning that you can start your study once IRB approval is received and forwarded to the FDA, but that there is additional information that needs to be provided. We will have 45 days from the date of the letter to respond. No one ever receives full approval on the first submission -- so we are pleased with conditional approval.

Enclosed are several pages from the IDE and the myopia protocol that were revised based on your review of the IDE document that I previously sent you. Please replace the existing pages with these and you will have a complete document as it was sent to the FDA. A few of the pages have no changes from previous in the text but need to be replaced because a revision we made changed the pagination. I am also including a copy of the cover letter and IDE cover page that was used. The cover page for the laser manual should be inserted in the

front of the Nevyas Excimer Laser Manual section towards the end of your book.

It's been a pleasure working with both of you on this project. Thanks for all your help in getting documents and information to me. As always, do not hesitate to contact me if you have any questions.

Best Regards,

Barbara S. Fant, Pharm.D.
President

cc: Arthur Jackson

Enclosures: Revised IDE Pages

Nevyas Eye Associates
In Sight

Volume 1 Issue 1 Spring 1999

Herbert J. Nevyas, M.D.
Refractive, Cataract and Corneal Surgery

Joann Y. Nevyas, M.D.
Cataract and Glaucoma Surgery and Therapy

Anita NevyasWallace,M.D.
Refractive, Cataract and Corneal Surgery

Ira B. Wallace, M.D.
Ophthalmic Plastic, Reconstructive Surgery and Cosmetic Surgery

Edward A. Deglin, M.D.
Vitreo-retinal Disease and Surgery

Mitchell E. Stein, M.D.
Retinal Disease, Glaucoma, Medical and Surgical Ophthalmology

Bari M. Brandt, M.D.
Vitreo-retinal Disease

Richard H. Sterling, O.D.
Interprofessional Relations
Refractive Surgery Coordinator
Network Administrator, NEECN

E-mail address: Nevyas@aol.com

Web Site: WWW.NEVYAS.COM

Inaugural Newsletter

We are proud to present to you our first newsletter for the purpose of informing you of activities within Nevyas Eye Associates (NEA), technological advances and opportunities to enhance your services and abilities. Over the last thirty years we have tried to present this type of information at our spring symposium annually but there is so much information and continuously changing technological advances and managed care issues to present that one day throughout a year is just not sufficient. This newsletter format will allow us to continually update you several times a year on various topics. Please feel free to contact our office if you have suggestions on future topics or have an article you'd like to present to our "audience". Each section of this newsletter will be researched and consultation with the appropriate specialist will enhance our presentation of information. We also hope that you take advantage of our free classified section so that we may assist our readers in the sale of equipment and/or identifying the appropriate associate or partner. You may simply fax your advertisement to *1-610-668-1509*, or send it to the attention of Dr. Richard Sterling at the Bala office of NEA.

Additionally, we will be utilizing our extensive lecture series throughout the year (45 credit hours over the calendar year 1999) to update you on the advances being made. Our newly redesigned website (*WWW.NEVYAS.COM*) shall act as a source of new information on our practice and the many projects we have undertaken to insure that Nevyas Eye Associates remains on top of the state-of-the-art.

Delaware Valley Refractive Surgery Partnership

Over four years ago we formed Delaware Valley Refractive Surgery Partnership (DVRSP) to offer a quality alternative refractive surgery practice to the optometric practitioner who was being "wooed" by venture capitalists investing in excimer laser technology. It has evolved into a 340 member group that has a credo of quality and excellence. Drs. Herbert Nevyas and Anita Nevyas-Wallace strive to improve an already precise procedure in LASIK. Dr. Herbert Nevyas has invented a fixation device that emits a very small amount of laser energy (1/4 milliwatt) but is visible while the flap is lifted even for the extremely high myope theoretically insuring centration. Since we began using this unique device we have all but eliminated significant decentration (>.5mm). Dr. Anita Nevyas-Wallace has developed a novel approach when utilizing a laser for the hyperopic astigmat. We are approaching 1,000 cases and have *attained 20/40 or better UCVA for 94%*

cont'd pg. 4

Inside This Issue:

"Oculoplastic comanagement is one more way NEA has tried to work more closely with our referring doctors".

Disc Appearance: A New Risk Factor For Glaucoma?

There are many risk factors for the glaucomatous optic nerve damage, systemic hypertension, systemic hypotension, diabetes, hemodynamic crisis, and myopia. Recently, another possible risk factor was investigated. Many researchers have looked at various glaucomatous disc appearances. Most notably, these include focal, myopic, sclerotic, and high-pressure types.

First, the focal ischemic type is a disc with localized tissue loss at the superior or inferior poles. Other areas of the neuroretinal rim are relatively intact. Myopic glaucomatous discs are tilted discs with myopic temporal crescents and additional evidence of glaucomatous damage. Senile sclerotc type is a disc with saucerized and shallow cup with peripapillary atrophy and choroidal sclerosis. The remaining neuroretinal rim is usually pale. Finally, high pressure type is a disc with diffusely enlarged, round cup without a localized defect.

Focal ischemic type is more common in middle aged or older women with normal or elevated intraocular pressures. Migraine is more prevalent in this group. The higher prevalence of migraine in the focal ischemic group suggests that vasospasm or whatever causes migraine could possibly be an important factor in the pathogenesis of the glaucomatous loss in this group. Also, this group has a higher prevalence of disc hemorrhage. The marked predominace of superior scotomas in the focal ischemic group corresponded to the great frequency of focal loss in the inferior pole. Patients with myopic glaucomatous discs are young men, more frequently asians in whom high myopia is quite common.

Patients with senile sclerotic discs are usually elderly and have normal or elevated IOP. They have a higher prevalence of microvascular disease manifesting as ischemic heart disease or systemic hypertension. Glaucoma patients with the high-pressure type are also young, *Cont'd next column*

Oculoplastic Comanagement

Ira Wallace, MD has remained at the forefront of technology in his chosen specialty, ophthalmic plastic and laser and laser reconstructive surgery. He is a board certified ophthalmic surgeon and a Fellow of the American Board of Cosmetic Surgery. With the advent of various laser technologies LASER eyelid surgery has become more popular because of reduced bruising, shorter recovery time and enhanced predictability of the result. At some of our recent continuing education lectures Dr. Wallace has presented his concept of comangement of the functional oculoplastic patient. This concept is just one more way the practice of Nevyas Eye Associates has tried to work more closely with our referring doctors. Many of the patients who enter your office are potential oculoplastic patients since Dr. Wallace has included in his armementarium of services CO2 Laser Skin Resurfacing, Erbium Laser Skin Resurfacing, Photoderm (eliminates veins and pigmented lesions without surgery), hair removal, HGM laser (eliminates spider veins, age spots, sun damage, scars and broken blood vessels), glycolic skin treatments, collagen implants and Botox treatment. For more information on how to introduce oculoplastic into your practice please call ***1-800-38-LASER*** or e-mail us at Nevyas@aol.com or look at Dr. Wallace's web site at WWW.LASER-COSMETIC.COM.

Disc appearance- cont'd

have elevated IOPs, and have less tendency to have disc hemorrhage.

In a pilot study of the rates and patterns of progression of damage four distinct types of glaucomatous optic discs were investigated. Results showed the high-pressure type was most common and there was a trend toward higher progression rates in the focal and myopic types, with focal patterns of progression

"One of the goals when forming our network was to put the individual practitioner in charge of his/her own destiny..."

Northeastern Eye Care Network, P.C.

North Eastern Eye Care Network, P.C. has recently sent out a newsletter to our network providers as well as many of the optometrist in the area. Since 1997, our first year in operation, we have signed contracts with two of the largest PPO's in the area and two payors that have HMO, PPO and several other insurance products and have recently tried to penetrate this market utilizing a large marketing team. One of our goals in forming this network was to put the individual practitioner in charge of his/her destiny while still having a say in how contracting takes place. We felt the dominant payors were unfairly increasing premiums while putting more restrictions on the health care providers. After several months of due diligence we have identified Mid Atlantic Medical Services, Inc.(MAMSI) as a payor that treats networks of providers with respect and is willing to offer extremely competitive insurance premium rates. We are still awaiting word on several other issues including, the Aetna US Healthcare "Pilot Eye Care Program"(potential carveout), additional provider contracting opportunities and inclusion in several local employer self insurance programs. We will begin the recredentialing process shortly and we welcome additional providers in our network. We are evaluating several claims adjudication systems to create a seamless transition into in-house claims at the Bala office. We have been audited and reviewed by the largest payors in the area and our credentialing process passed them all. The ultimate goal of our network is to maintain our presence in the vision care contracting arena and to put new patients in our network providers examination chair. If you should need further information on our network please call:

1-610-668-7416

Is the theory of accomodation changing?

Accomodation is historically described as the progressive thickening of the lens due to zonular relaxation with ciliary muscle contraction or the loss of accomodation is due to decreasing elasticity of the lens fibers in the capsule. Dr. Hideharu Fukasaku believes that with accomodative effort, the ciliary body becomes rounded and elogated, pointing more centrally toward the lens equator. The anterior/posterior zonules relax, then the central lens thickens and accomodation occurs. He believes presbyopia results from continuous growth of the lens constricted by the sclera which stops growing at puberty. This process crowds the posterior chamber, shortens the length of pull for the ciliary muscle/zonular complex, and causes a decreased anterior movement of the lens. Spencer Thornton, MD developed a procedure called anterior ciliary sclerotomy based on the theory that radial incisions of the the sclera overlying the ciliary body would cause an increase in the circumference of the globe, allowing the ciliary body more room, with an increased accomodative power of the eye.

Dr. Fukasaku did a study consisting of eight men and four women, from 48 to 66 years of age with an amplitude of accomodation ranging from 1.3 to 2.2D of accomodation preoperatively. Utilizing Dr. Thornton's procedure the mean amplitude of accomodation increased 1.9D. Dr. Herbert Nevyas has tried this technique on a few patients and the results seem to be very promising. The theory is that scleral relaxing incisions will follow the principles of radial keratotomy but the results are still too conflicting and it is too early to tell. But, in the near future you may have an alternative for the early presbyope beyond bifocals or reading glasses. We'll keep you posted on the research that is currently underway in presbyopia surgical treatment.

"The surgeons of NEA will do the appropriate technique for your patients needs and wants"!!

Refractive Lensectomy

Removing the cataractous crystalline lens by phacoemulsification and introcular lens implant has been utilized at NEA for several decades. It is only relatively recently that removing the clear lens of a 40 year old for refractive reasons has become popular. For the very high myope or relatively high hyoperope this may be the only alternative. The population of refractive surgery patients seems to beprimarily between 35-50 years of age. These people are aware of their impending presbyopia. Their accomodation is limited at best in this age group so that the removal of the natural crystalline lens for this population would not have the dramatic effect on accomodation as it might for the twenty year old. By removing the lens we not only eliminate the possiblility of eventual cataracts but "induce" an optical zone similar to the natural zone compared to a decrease in effective optical zone induced by LASER ablation. A larger optical zone will reduce the chance of having glare being a major issue for the high myope having LASIK. As we continue to decrease the chances of Cystoid Macular Edema with the advent of better NSAIDs refractive lensectomy becomes a very viable alternative for many of your patients that up until now were not considered refractive surgery patients. Phacoemulsification must now be included when discussing vision correction alternatives. The most important issue regarding refractive surgery is that the surgeons of NEA will do the appropriate technique for your patients ametropia and their visual needs.

Notes

This past year we have seen a great response to our lecture presentations (calendar for the remainder of the year on the next column) with the available seating utilized. *Please call in advance to hold your reservation since seating is limited.*

DVRSP cont'd

and 20/20 or better in over 50% of our cases. We have begun a marketing campaign in April of 1999 with our ads in Philadlephia Magazine and a radio ad appearing on WIP radio, on the AM dial. We offer to our members, training for their staff, attractive posters highlighting your refractive surgery services, pamphlets for marketing of your services and cooperative advertising dollars. Others might say they have the only FDA appoved excimer laser for LASIK but the truth is our excimer is under IDE approval by the FDA. We strive to put patients in your offices for your comanagement services. If you believe and understand the precision and technology available to the ametropic patient we feel you'll be more inclined to offer it to all of your patients as a vision correction alternative

Upcoming Network Sponsored Lecture Activities

Wednesday June 2, 1999 6-10 pm
Dry Eye Syndrome: Punctal Occlusion and Hands-On Workshop
Staff of NEA & Punctal Occlusion Experts
Twelve Caesar's Hotel & Convention Ctr.
Philadelphia, PA

Wednesday September 22, 1999 7-10pm
Therapeutic Update
Drs. Herbert Nevyas & Mitchell Stein
Giovi's Restaurant, Yardville, NJ

Wednesday September 29, 1999 8am-5pm
Camden Optometric Center Symposium
Staff of NEA
Mt. Laurel, NJ

Monday October 11, 1999 7-9pm
Retinal Pathology Update-Dx and Tx
Dr. Edward Deglin
Bala Cynwyd, PA

Wednesday November 3, 1999 7-9pm
Glaucoma-Diagnosis and Treatment
A Hands-On Lecture and Workshop
Drs. Joann Nevyas & Mitchell Stein
Bala Cynwyd, PA

Monday November 22, 1999 7-9pm
Refractive Surgery- The Newest Therapies
Drs. Herbert Nevyas & Anita Nevyas-Wallace
Bala Cynwyd, PA

Wednesday December 1, 1999 7-9pm
The Red and Dry Eye; Therapeutic Decisions
Dr. Mitchell Stein
Bala Cynwyd, PA

1-800-9-LASER-6

SCHULMAN ASSOCIATES INSTITUTIONAL REVIEW BOARD, INC. (SAIRB)
REPORT FORM

IRB#: 1997-1942-0
INVESTIGATOR: Herbert J. Nuyas, MD
SPONSOR: Nuyas Eye Associates
PROTOCOL#: NEV-97-001

PLEASE CHECK ONE
☐ INTERIM STATUS
☑ ANNUAL REVIEW
☐ FINAL REPORT

1. Are any subjects still participating in this study? ☑ Yes ☐ No
If "No", please check the following that apply:
☐ Study Closed ☐ No subjects enrolled ☐ Study on Hold ☐ Investigator Withdrawn ☑ Other: Follow up only

2. Is enrollment open or closed at your site? ☐ Open ☑ Closed

3. List the date the first subject was consented at your site: 8/28/97

4. Does this study have an amendment to extend this protocol? ☐ Yes ☑ No
Is your site participating in the extension? ☐ Yes ☐ No What is the IRB #?: _____

5. Does this protocol have a sub-study? ☑ Yes ☐ No (All substudies are complete)
Is your site participating in the sub-study? ☑ Yes ☐ No

6. If submitting an **Interim Status** or **Annual Review** report, what is the *expected* date of completion: December 2004
If a **Final Report**, what was the date of final visit of the last study subject: _____

7.

	Number of Subjects	Extension (if applicable)	Extension (if applicable)
Consented	779	N/A	N/A
Randomized	N/A	N/A	N/A
Dropped after randomization	N/A	N/A	N/A
Completed	327	N/A	N/A

8. List *specific reasons for each randomized subject* who has dropped, *since the last submitted report* (if additional space is needed, please use a separate sheet of paper and attach to this form):

N/A

9. Since your last report, have you consented any subjects from the following groups? (please check all that apply) **If yes, copies of each signed consent must be submitted with this report.** NO

☐ Anyone under the age of majority in your state
☐ Anyone using a legally authorized representative (such as a parent, legal guardian or healthcare power of attorney)
☐ Non-English speaking persons
☐ Anyone who cannot read (illiterate subjects)
☐ Visually impaired persons

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10. Copies of each of the following, *signed by the last subject consented*, must be submitted with this report, unless previously submitted.
- What is the approval date of the consent form currently in use? 8/20/97 ☐ Attached ☐ N/A
- What is the approval date of the addendum consent form currently in use? _____ ☐ Attached ☐ N/A
- What is the approval date of the sub-study consent form currently in use? _____ ☐ Attached ☐ N/A

No new subjects since last report; last informed consent previously submitted

SCHULMAN ASSOCIATES INSTITUTIONAL REVIEW BOARD, INC. (SAIRB)
REPORT FORM

11. Indicate whether each of these events OCCURRED AT YOUR SITE SINCE YOUR LAST REPORT.

• Serious Adverse Events	☐ Yes	☑ No	# of SAEs _____
• Significant Protocol Deviations	☐ Yes	☑ No	
• Protocol Amendments	☐ Yes	☑ No	
• Advertisements / Recruiting Material	☐ Yes	☑ No	
• Broadcast, Video or Audio Recruitment Material	☐ Yes	☑ No	
• Change of Site Location	☐ Yes	☑ No	
• Change in Subject Compensation	☐ Yes	☑ No	
• Change of Principal Investigator	☐ Yes	☑ No	
• Change of Sub Investigator	☐ Yes	☑ No	

12. *Since your last report*, has there been any IND safety information reported to your site? ☐ Yes ☑ No
If "Yes", has this information been reported to SAIRB?

13. *Since your last report*, have you advised your subjects of any *additional* information not contained in an SAIRB approved document that may affect their willingness to stay in the study? ☐ Yes ☑ No
If "Yes", provide written explanation of the information provided.

14. Have any subjects sought compensation for injury from the study? ☐ Yes ☑ No
If "Yes", provide a written explanation on a separate page.

15. Have you received any complaints from subjects as to the conduct of the study? ☑ Yes ☑ No
If "Yes", provide a written explanation on a separate page.

16. Has anything occurred in this study which, in your opinion, would alter the IRB's initial risk/benefit analysis? ☐ Yes ☑ No
If "Yes", please explain the reasons for your opinion in detail on a separate page.

17. Have there been changes in the status of board certification, licensure, or hospital privileges of any investigator on this study? ☐ Yes ☑ No
If "Yes", please describe fully on a separate page.
If license renewal, please attach copy

18. Are there any criminal charges or medical board complaints pending against any of the investigators on this study? ☐ Yes ☑ No
If "Yes", please describe fully on a separate page and attach copies of any relevant documents.

19. Has your site been audited during this study? ☑ Yes ☐ No
If "Yes", by whom was the audit conducted? ☑ FDA ☑ Study Sponsor ☐ IRB ☐ Other:

What was the date of the audit? Previously reported

List the name of the Investigator who was the subject of the audit? Herbert J. Neuyas, MD

Copy of the FDA audit report attached? ☐ Yes ☑ Previously submitted ☐ Not available at this time

20. Since your last report, have you had an IRB terminate or suspend its approval of a study at your site? ☐ Yes ☑ No

21. Since your last report, have you had an IRB impose restrictions or sanctions on a study at your site? ☐ Yes ☑ No

22. Since your last report, have you had an IRB refuse to review a protocol for any investigator at your site? ☐ Yes ☑ No

If you answered "Yes" to # 20, 21 or 22, you must provide a detailed explanation and supporting documents on a separate page.

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7/1/02 14:21

SCHULMAN ASSOCIATES INSTITUTIONAL REVIEW BOARD, INC. (SAIRB)
REPORT FORM

Name of person to contact at your site regarding this report: Richard H Sterling, OD

Phone #: 610-668-7416 Best time to call: M-F 9-5
Fax #: 610-668-1509 E-Mail: Nevyas@aol.com

Name of CRA (Monitor) for this study:

Company: Clinical Research Consultants, Inc.
Address: 3307 Clifton Ave. Cincinnatti, OH 45220
Phone #: 513-961-5200 Best time to call: 7-5pm
Fax #: 513-961-2858 E-Mail: BSFANT@CRC-Regulatory.com

I acknowledge that I have thoroughly reviewed the information provided on this report form. I also acknowledge that the information provided in response to the questions of Schulman Associates Institutional Review Board, Inc. (SAIRB) is true and accurate.

Signature of Principal Investigator *(Required)* Date

NYA 01938

SCHULMAN ASSOCIATES INSTITUTIONAL REVIEW BOARD
10 Knollcrest Drive, Suite 200, Cincinnati, OH 45237
513-761-4100 fax 513-761-1460

Study Status Notification

DATE: August 1, 2001

TO: Richard Sterling, O.D.
Nevyas Eye Associates

FROM: Sandy Stagge, R.N., B.S.N., IRB Coordinator
Schulman Associates Institutional Review Board

RE: Safety and Effectiveness of the Nevyas Excimer Laser for the Treatment of Hyperopia Using a Spherical Ablation Algorithm (Apollo Software)
(Protocol # NEV-97-003) **Sponsor:** Herbert Nevyas **IRB#:** 01-2898-0

Safety and Effectiveness of the Nevyas Excimer Laser for the Treatment of Myopia Using a Spherical Ablation Algorithm (Apollo Software)
(Protocol # NEV-001-002) **Sponsor:** Herbert Nevyas **IRB#** 01-2902-0

The Board reviewed the above-mentioned protocols and informed consents at the August 1, 2001, meeting and identified issues to be addressed by the sponsor or principal investigator. The study status is *On Hold* pending response to the following:

1. Section 10.4 in both protocols indicates that "a monitor will be designated to oversee the progress of the investigation. The monitor may be an employee of the sponsor-investigator or a consultant to the sponsor-investigator." *To minimize conflict of interest, the Board requests that an outside consultant be chosen as the monitor for these two studies.*
2. Section 8.4 indicates that a subject questionnaire will be completed during the noted follow-up visits. *The Board requests a copy of this questionnaire for review.*
3. The Patient Information and Consent Form for Bilateral Simultaneous LASIK includes the following statements: "In the United States, the FDA considers LASIK to be a practice of medicine issue between a doctor and a patient. As such, LASIK becomes an "off label" use of an approved excimer laser. The LASIK procedure has not received FDA approval since no laser manufacturer has applied for approval." *The Board requests further clarification regarding these statements.*

In addition, due to the nature of the procedures involved in these two studies, the Board is requesting an expert review by a consultant of the Board's choosing. Upon review by the consultant, if further issues or concerns are noted, these will be forwarded to you.

The Board requests your written response to these currently identified issues. In order for your response to be reviewed at the next Board meeting, Wednesday, August 8, 2001, SAIRB must be in

SCHULMAN ASSOCIATES INSTITUTIONAL REVIEW BOARD
10 Knollcrest Drive, Suite 200, Cincinnati, OH 45237
513-761-4100 fax 513-761-1460

receipt of your documented response no later than Tuesday, August 7, 2001, 11 am EST. Failure to meet this deadline will result in an additional week's delay in the review of your study. You may submit your response to me via:

- FAX: 513-761-1460
- E-mail: sstagge@sairb.com

Thank you for your assistance with the above-mentioned study. You may contact me at 513-761-4100, x120 if you have concerns or questions about these matters.

Nevyas Eye Associates / Delaware Valley Laser Surgery Institute
Ambulatory Surgery Center

COMANAGEMENT REQUEST FORM

Herbert J. Nevyas, M.D.
Refractive, Cataract, and Corneal Surgery

Joann Y. Nevyas, M.D.
Cataract and Glaucoma Surgery and Therapy

Anita Nevyas-Wallace, M.D.
Refractive, Cataract, and Corneal Surgery

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Edward A. Deglin, M.D.
Vitreo-retinal Disease and Surgery

Mitchell E. Stein, M.D.
Retinal Disease, Glaucoma Medical and Surgical Ophthalmology

Joseph M. Ortiz, M.D.
Glaucoma Surgery and Therapy Medical and Surgical Ophthalmology

Carl M. Brandt, M.D.
Vitreo-retinal Disease

Donelson R. Manley, M.D.
Ocular Motility, Pediatric Ophthalmology

Richard H. Sterling, O.D.
Interprofessional Relations Refractive Surgery Coordinator

I understand and consent to the fact that Dr. _____, a licensed eye doctor will provide my postoperative care following my eye surgery. I have discussed this with Dr. _____ and have been told Dr. _____ has been trained on the proper protocols and procedures for follow-up services for my refractive surgery. I have also been assured that the surgeons of NEA will be in contact with my eye doctor throughout the recooperative process, and if complications should arise resulting from the surgery they will be contacted immediately. I understand my payment obligations to Nevyas Eye Associates and Dr. _____ and all of the other information that has been presented to me about my postoperative care, and voluntarily consent to this co-management arrangement. I further authorize Dr._____, Dr. _____ and other health care personnel involved in performing this procedure and providing care, to share with one another information relating to my health, my vision, or this procedure that they deem relevant to providing me with appropriate care.

_____ _____
Patient Date

_____
Patient Signature

_____ _____
Witness Name Date

_____
Witness Signature

_____ _____
Surgeon Name Date

_____
Surgeon Signature

_____ _____
Co-manager's Name Date

NYA 02266

_____
Co-manager's Signature

☐ Two Bala Plaza
333 East City Avenue
Bala Cynwyd, PA 19004
610-668-2777
Fax 610-668-1509

☐ 20th Floor
1930 Chestnut Street
Philadelphia, PA 19103
215-561-1411
Fax 215-564-0052

☐ Central Square
2465 Grant Avenue
Philadelphia, PA 19114
215-673-2020
Fax 215-969-6375

☐ 1001-E Lincoln Drive West
Greentree Executive Campus
Marlton, NJ 08053
856-985-9797
Fax 856-985-1191

e-mail address:
nevyas@aol.com

Nevyas Eye Associates / *Delaware Valley Laser Surgery Institute*
Ambulatory Surgery Center

REFRACTIVE SURGERY
FINANCIAL AGREEMENT

Herbert J. Nevyas, M.D.
Refractive, Cataract, and Corneal Surgery

Joann Y. Nevyas, M.D.
Cataract and Glaucoma Surgery and Therapy

Anita Nevyas-Wallace, M.D.
Refractive, Cataract, and Corneal Surgery

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Donelson R. Manley, M.D.
Ocular Motility, Pediatric Ophthalmology

Richard H. Sterling, O.D.
Interprofessional Relations Refractive Surgery Coordinator

Patient Name: _____

Surgical Procedure: _____

Date of Surgery: _____

Insurance Coverage: _____

Fees of Surgery:

• **Radial and/or Astigmatic Keratotomy**	**$2,000.00 per eye**
• **Laser Intrastromal Keratomileusis (LASIK)**	**$2,500.00 per eye**
• **Laser Thermal Keratoplasty (LTK)**	**$2,500.00 per eye**
• **INTACS**	**$3,000.00 per eye**
• **Refractive Lensectomy with Intraocular Lens Implant**	**$4,000.00 per eye**

Financial Agreement Terms:

$_____ Payable to Nevyas Eye Associates

$_____ Payable to comanaging optometrist (if applicable):

Dr. _____

Payment in full for both eyes is due a minimum of 10 days prior to surgery.

I understand most insurance plans do not cover refractive eye surgery and I am responsible for the fee. I have agreed to pay for the services rendered as per the above payment terms.

_____ _____
Patient Signature Date

_____ _____
Nevyas Eye Associates, P.C. Date

NYA 02267

e-mail address:
nevyas@aol.com

☐ Two Bala Plaza
333 East City Avenue
Bala Cynwyd, PA 19004
610-668-2777
Fax 610-668-1509

☐ 1528 Walnut Street
Suite 1501
Philadelphia, PA 19102
215-790-0661
Fax 215-790-0652

☐ Central Square
2465 Grant Avenue
Philadelphia, PA 19114
215-673-2020
Fax 215-969-6375

☐ 1001-E Lincoln Drive Wes
Greentree Executive Camp
Marlton, NJ 08053
856-985-9797
Fax 856-985-1191