NATIONAL ARBITRATION FORUM

DR. HERBERT NEVYAS *DR. ANITA NEVYAS* *NEVYAS EYE ASSOCIATES* Two Bala Plaza, PL-33 333 E. City Avenue Bala Cynwyd, Pennsylvania 19004 *US* **(Complainants)** v. *DOM MORGAN* *P.O. Box 1011* *MARLTON, NJ 08053* **(Respondent)**	)	**Domain Names In Dispute:** *NevyasLasik.com* *HerbertNevyasLasik.com* *AnitaNevyasLasik.com* **Case Number:** FA1007001333710

RESPONSE

Respondent (Morgan) received a Notification of Complaint and Commencement of Administrative Proceeding on July 6, 2010 via electronic mail and the formal commencement on July 22, 2010 also via electronic mail. The Notification stated that Complainant had submitted a Complaint for decision in accordance with the Uniform Name Dispute Resolution Policy (UDPR), adopted by the Internet Corporation for Assigned Names and Numbers (ICANN) on August 26, 1999 and approved by ICANN on October 24, 1999, and the Rules for Uniform Domain Name Dispute Resolution Policy (UDPR Rules), with an effective date of March 1, 2010, and the National Arbitration Forum (FORUM) Supplemental Rules (Supp. Rules). UDPR Rule 3(b)(i).

1) **RESPONDENT INFORMATION**

a) Name: Dom Morgan
b) Address: PO BOX 1011, MARLTON, NJ 08053
c) Telephone: 610-364-3367
d) E-Mail: lasiksucks4u@yahoo.com

2) The Respondent's (Morgan) preferred method for communications directed to the Respondent in the administrative proceeding: ICANN Rule 5(b)(iii).

a) Electronic-Only Material

i) Method: e-mail
ii) Address: lasiksucks4u@yahoo.com
iii) Contact: Dom Morgan

b) Material Including Hard Copy

i) Method: Mail
ii) Contact: Dom Morgan
iii) Address P.O. Box 1011 Marlton, NJ 08053

3) The Respondent (Morgan) chooses to have this dispute heard before a single-member administrative panel as stated in the Complainant's Complaint.

THE COMPLAINANT(S) COMES BEFORE THE NATIONAL ARBITRATION FORUM WITH UNCLEAN HANDS

Complainant(s) have a history of misrepresenting facts to impede Respondent Morgan's First Amendment Rights. Complainant(s) through their counsel prior to the onset of litigation in the Nevyas v. Morgan lawsuit have stated "that this website should be removed in its entirety"[1] and have repeatedly harassed Respondent Morgan's website hosting providers with threats of lawsuit. Complainant(s) twice attempted to obtain a restraining order against Respondent Morgan which was denied by the Philadelphia Court of Common Pleas. Complainant(s) then brought suit against Respondent Morgan in Federal Court. The federal district court dismissed the Lanham Act claim because the plaintiffs lacked standing to bring a false advertising claim and because Morgan's statements did not qualify as "commercial advertising or promotion." Unhappy with the Federal Court decision, Complainant(s) reinstated their claims in the state court for defamation, breach of contract and specific performance which proceeded to trial in July 2005. The trial court granted an injunction in favor of the plaintiffs (complainant(s)). On appeal, the Superior Court of Pennsylvania vacated the injunction in March 2007 and remanded the case to the trial court for further findings and proceedings.[2] Claimant(s) allege that Respondent Morgan posted numerous false, disparaging and defamatory statements regarding Complainants are not true and have yet to be determined by the courts. In addition, facts Respondent Morgan and his co-defendant submitted during litigation resulted in the Judge ruling that Complainant(s) were public figures.[3]

THE COMPLAINANT(S) ARE A RISK TO PUBLIC SAFETY

[1] Exhibit 1 - http://www.lasikdecision.com/media2/nocontract.pdf
[2] Exhibit 2 - http://www.citizen.org/documents/nevyasmorganopinion.pdf
[3] Exhibit 3 - https://fjdefile.phila.gov/dockets/zk_fjd_public_qry_03.zp_dktrpt_frames?case_id=031100946

Misrepresentations to Schullman Associates, Complainant(s) Institutional Review Board (IRB) and the U.S. Food and Drug Administration during their investigational study for LASIK have resulted in:

(a) Damages to over 30 people by claimant(s);
(b) Numerous letters from the FDA stating claimant(s) were in violations of their study;[4]
(c) Discontinuance of their study by the FDA for safety reasons;

As such, the public has a right to know they are at risk when choosing services by claimant(s).

4) RESPONSE TO FACTUAL AND LEGAL ALLEGATIONS MADE IN COMPLAINT

a) This Response specifically responds to the statements and allegations contained in the Complaint and includes any and all bases for the Respondent to retain registration and use of the disputed domain name.

b) First and foremost, it is important to note at the outset that this is a case about Internet gripe sites in which the names of the Complainants – Herbert and Anita Nevyas -- have been used in the domain names for sites that are devoted to describing Respondent's criticisms of those Complainants. Even assuming that their names can be the subject of a trademark-like UDRP complaint, this UDRP proceeding should take account of constitutional and trademark law in the United States, where the validity of any decision by the UDRP panel will be contested. And courts in the United States have consistently held that trademark claims over domain names in the form www.trademark.com cannot be brought when the domain name is used for a web site that is **about** the trademark holder, so long as the web site itself is not confusing about whether it is sponsored by the trademark holder. *Lighthouse Ministry v. Foundation for Apologetic Information and Research*, 527 F.3d 1045 (10th Cir. 2008); *Lamparello v. Falwell*, 420 F.3d 309 (4th Cir. 2005), *rev'g* 360 F. Supp 2d 768 (E.D.Va. 2004); *Lucas Nursery and Landscaping v. Grosse*, 359 F.3d 806 (6th Cir. 2004); *Taubman v. WebFeats*, 319 F3d 770 (6th Cir. 2003). Indeed, the First Amendment limits trademark law to commercial uses. *Id.* Consequently, it is an independent ground for objecting to the application of trademark law to the use of domain names like those at issue here that the use is for the non-commercial purpose of expressing opinions about the trademark holder. *Lighthouse Ministry v. Foundation for Apologetic Information and Research*, 527 F.3d 1045 (10th Cir. 2008); *Bosley Medical v. Kremer*, 403 F.3d 672 (9th Cir. 2005); *TMI v. Maxwell*, 368 F.3d 433 (5th Cir. 2004); *Taubman v. WebFeats*, 319 F3d 770 (6th Cir. 2003).

c) The domain names <*nevyaslasik.com*>, <*anitanevyaslasik.com*>, and <*herbertnevyaslasik.com*> (sites listed) are not identical or confusingly similar to a trademark or service mark in which the Complainant(s) claims to have rights.

[4] Exhibit 4 - http://www.lasikdecision.com/index.php?option=com_content&view=category&layout=blog&id=33&Itemid=114 – under section 'Nevyases Investigational Study'

i) It is impossible for visitors to (sites listed) to be confused into thinking that they are visiting complainant(s) web site. A simple perusal of the home pages of (sites listed) makes it immediately obvious that the sites are designed to openly show Respondent Morgan's experience with claimant(s) and what can happen if you are not a good candidate for LASIK. The first caption of each website states: "**After damaging my eyes with Refractive Surgery, Drs. Herbert Nevyas and Anita Nevyas-Wallace of Nevyas Eye Associates sued to silence me."** No person of average intelligence could conclude that an organization would operate a web site to show they damaged people and impeded on a person's First Amendment Rights. Furthermore, there are many statements and links on the sites that encourages the visitor to verification of comments made on respondent Morgan's sites. In lieu of complainant(s) argument, as of July 29, 2010 the websites now reads: <*nevyaslasik.com*> "Why I do not recommend Nevyas Eye Associates!", <*anitanevyaslasik.com*> "Why I do not recommend Anita Nevyas!", and <herbertnevyaslasik.com> "Why I do not recommend Herbert Nevyas!". The title pages of each site have also been changed to further reflect these sites are not complainant(s).

d) Respondent owns < *nevyaslasik.com*>, < *anitanevyaslasik.com*>, and < *herbertnevyaslasik.com*> and has rights and legitimate interests in that is/are the subject of the complaint. ICANN Rule 3(b)(ix)(2); ICANN Policy ¶ 4(a)(ii).

i) The Respondent is making a legitimate noncommercial or fair use of the domain name, without intent for commercial gain to misleadingly divert consumers or to tarnish the trademark or service mark at issue, establishes a legitimate interest in the domain name. UDRP panels have stated repeatedly that criticism of a trademark owner's activities is a fair use, even if the domain name incorporates the Complainant's trademark. See, e.g., *Bridgestone Firestone, Inc. v. Myers*, WIPO Case No. D2000-0190 (July 6, 2000); *Bosley Med. Group v. Kremer*, WIPO Case No. D2000-1647 (February 28, 2001); *TMP Worldwide Inc. v. Potter*, WIPO Case No. D2000-0536 (August 5, 2000); *The Am. Nat'l Red Cross v. Mafiabusters.com LLC*, NAF File No. FA0206000114589 (August 6, 2002); *Pensacola Christian College Inc. v. Gage*, NAF File No. FA0110000101314 (December 12, 2001*); Compusa Mgmt. Co. v. Customized Computer Training*, NAF File No. FA0006000095082 (August 17, 2000); *Robo Enters., Inc. v. Daringer*, NAF File No. FA0101000096375 (February 21, 2001); *Savin Corp. v. savinsucks.com*, NAF File No. FA0201000103982 (March 5, 2002); *Bloomberg L.P. v. Secaucus Group*, NAF File No. FA0104000097077 (June 7, 2001); *Mayo Found. for Ed. and Research v. Briese*, NAF File No. FA0102000096765 (May 4, 2001); *Dorset Police v. Coulter*, eRes Case No. AF-0942 (October 20, 2001); *Carefree Toland Pools, Inc. v. Thomson*, eRes Case No. AF-1012 (October 30, 2001); cf. *Wal-Mart Stores, Inc. v. MacLeod*, WIPO Case No. D2000-0662 (September 19, 2000) (stating that criticism can be a legitimate interest, but finding no legitimate interest because the protest site was created only as a pretext for selling the site back to the trademark owner*); Becker & Poliakoff, P.A. v. Isabell*, eRes Case No. AF-0847 (August 9, 2000) (stating the panel would find criticism to be a legitimate fair use if it had not decided the dispute on other grounds).

Respondent Morgan also is not a commercial enterprise and the sole purpose of his

websites are to provide verifiable, factual information about respondent Morgan's experiences with complainant(s). Although the information provided on Respondent's web site admittedly is, and should be, embarrassing to complainant and its LASIK surgeons, complainant has not provided any evidence to support his allegation that it is defamatory.

There is significant social value in permitting people to express their opinions as part of their First Amendment rights, just as there is a right to criticize public figures and organizations under the freedom of speech principles of the U.S. Constitution. These rights clearly override the minimal commercial value of a domain name in a case like this.

ii) The accuracy and legitimacy of respondent Morgan's claims about complainant(s) on < *nevyaslasik.com*>, < *herbertnevyaslasik.com*>, and < *anitanevyaslasik.com*> are confirmed by the public documents throughout Respondent Morgan's websites.

c) Respondent has not registered < *nevyaslasik.com*>, < *anitanevyaslasik.com*>, and < *herbertnevyaslasik.com*> in bad faith ICANN Rule 3(b)(ix)(3); ICANN Policy ¶ 4(a)(iii).

i) Respondent Morgan has not offered to sell the domain names to any entity. Respondent Morgan has simply acquired the domain names for the purpose of educating the public due to claimant(s) risk to public safety and past improprieties which the complainant(s) engages.

ii) Complainant(s) allege Respondent Morgan profits from the domains. This is simply not true. Most Lasik websites are advertisements for having Lasik eye surgery. These sites will list complications but severely downplay the risks associated with LASIK just to sell you the procedure. The same can be said of MANY doctors who perform this procedure when you go in for consultation. Most domains listed are third party sites by others damaged by Refractive Surgery, sites useful for those seeking information regarding LASIK that doctors just do not emphasize. The website < *lasikinfocenter.com*> claimant(s) emphasized was previously owned by Ariel Berchadsky, a New York lawyer who was damaged by refractive surgery.[5] Respondent Morgan does not earn any click-through fees or commissions from the web sites posted at the contested domain names. He does not profit from them in any way. All of the links in the 'Links' section of Respondent Morgan's websites have been chosen because, in the opinion of Respondent Morgan, they offer useful information to prospective patients who are considering surgery on their eyes, or to other lasik victims like Respondent Morgan who are trying to learn what they can do about what has been done to them. If some of those sites are mounted by professionals in the field, who hope that viewers will be choose their services, that is not why Respondent Morgan has linked to them and in particular the link goes to the informational pages on such web sites, not to pages that advertise the services of their creators. Respondent Morgan acknowledges changes are required to update sites and will do so accordingly (already started). Complainant also makes an issue of the fact

[5] Exhibit 5 - The link for lasikinfocenter.com has since been removed from the sites listed.

that, on a different web site that does not contain any of Complainants' names in the URL, Respondent Morgan urged public support for Public Citizen,[6] a not for profit organization and accepts no government or corporate money – they rely solely on foundation grants, publication sales and support from their members. As previously noted, Public Citizen's litigation group represented Respondent Morgan in a successful appeal from an injunction against the maintenance of that web site. But there is no appeal for support for Public Citizen on any of the web sites at issue in this case and, in any event, the United States Court of Appeals has specifically held than an expression of support for Public Citizen, along with a link to its web site, by one of its clients in a domain name case did not make that web site "commercial" and hence amenable to suit under the trademark laws. *Bosley Medical Institute v. Kremer,* 403 F.3d 672, 678 (9th Cir. 2005)

iii) A consensus has not yet developed among panels regarding whether an individual can have a legitimate interest in using a domain name in the form <trademark.com> for the purpose of criticizing or commenting on the trademark owner. Compare *Bosley Med. Group,* WIPO Case No. D2000-1647 (using <trademark.com> to comment on trademark owner is fair use), *with Nintendo of Am. v. Jones*, WIPO Case No. D2000-0998 (November 17, 2000) ("Insofar as a domain name which is identical to a name or mark is used solely in the context of the product of the owner of the name or mark and the owner objects to the use, it is not legitimate."). In the absence of a consensus, a panel must consider the parties' arguments and relevant legal authorities and then make a decision consistent with the goals of the Policy and the Rules, as well as general legal principles. See Rules Paragraph 15(a) ("A Panel shall decide a complaint on the basis of the statements and documents submitted and in accordance with the Policy, these Rules and any rules and principles of law that it deems applicable."). Moreover, as discussed above, because Complainant has accepted jurisdiction for judicial review in the United States, the panel should apply United States law, including both the First Amendment and the many court decisions limiting the use of trademark law to domain names for non-commercial web sites about the trademark holder.

Prior panel decisions finding no legitimate interest in using a domain name in the form of <trademark.com> for the purpose of criticizing or commenting on the trademark owner all relate to a trademark owner that is a commercial enterprise. Complainant claims to offer a "non-profit" service. Respondent also does not offer or provide any goods or services through its web site, nor does it solicit or accept donations. Accordingly, there is no intent to divert nor effective diversion of any commerce, nor any risk of misdirected donations. Respondent has neither sought nor received any commercial gain from the registration and use of the domain name.

iv) The panel in *Legal & Gen. Group Plc v. Image Plus*, D2002-1019 (WIPO Dec. 30, 2002), found that initial interest confusion was displaced by the criticism content at the respondent's web site and that such a "low level of confusion is . . . a price worth paying to preserve the free exchange of ideas via the Internet." *In Elm Grove Dodge*

[6] Exhibit 6 - http://www.citizen.org/Page.aspx?pid=2306

Chrysler Jeep, Inc. v. Schedule Star, FA 352423 (Nat. Arb. Forum Dec. 27, 2004), the panel came to a similar conclusion, finding no bad faith registration or use where the respondent "only registered the disputed domain names to voice concerns and complaints about Complainant" and "[n]o one reading the web site would be confused as to sponsorship."

v) Complainants also protest at length about the way Respondent Morgan "advertises" his web site in Google. Respondent does not "advertise" on Google – Google crawls web sites, identifies sites that are believed to be relevant to search queries using its sophisticated algorithm, and then returns search results accordingly. And it is Google, not Respondent, that decides how to describe the sites being returned, drawing text from the sites themselves. Each of the items about which the Nevyases complain are "organic" search results whose placement and content are determined solely by Google in its own discretion. Moreover, the courts do not agree with the implicit argument by complainants that the content of search listings makes out a basis for trademark litigation. No case based on the theory of "initial interest confusion" can be made out when a user of a search engine clicks on a search result and comes to a landing page that so clearly dispels any possible confusion as Respondent's pages do, by expressly criticizing the trademark holder. And, even if there were a possible trademark claim, it would not be a UDRP claim which is based only on the content of the domain name.

vi) Complainant(s) have presented a bizarre and baseless claim to the National Arbitration Forum that clearly emphasizes Respondent Morgan's claims that claimant(s) continuously impede on Respondent Morgan's First Amendment Rights and the harassment to silence him.[7]

5) RESPONSE TRANSMISSION

Respondent Morgan asserts that a copy of the Response, as prescribed by NAF's Supplemental Rules, has been sent or transmitted to the Complainant(s), in accordance with ICANN Rule 2(b). ICANN Rule 5(b)(vii); NAF Supp. Rule 5.

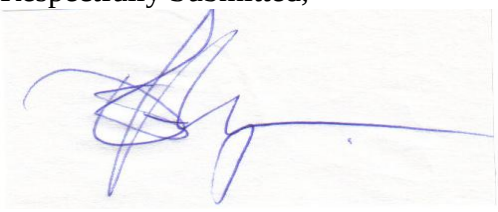
6) Respondent Morgan respectfully requests that the Administrative Panel denies the remedy requested by the Complainant(s).

7) CERTIFICATION

Respondent Morgan certifies that the information contained in this Response is to the best of Respondent's knowledge complete and accurate, that this Response is not being presented for any improper purpose, such as to harass, and that the assertions in this Response are warranted under these Rules and under applicable law, as it now exists or as it may be extended by a good-faith and reasonable argument.

[7] Exhibit 7 – Claimant(s) wrote this letter over 7 years after Respondent Morgan last saw them as a patient. Respondent Morgan believes the actions of claimant(s) was of vindictive nature and to further harass Morgan.

Respectfully Submitted,



_____

Dominic J. Morgan, Respondent

Exhibit 1

LAW OFFICES

Stein & Silverman, P.C.

230 So. Broad Street, 18th Floor
Philadelphia, PA 19102

ELIAS H. STEIN
LEON W. SILVERMAN
ALLISON LAPAT
ANDREW LAPAT

Telephone: (215) 985-0255
Telecopier: (215) 985-0342

August 14, 2003

Via Fax 610-789-9989
Steven A. Friedman, Esquire
850 West Chester Pike
Havertown, PA 19083

RE: Morgan v. Nevyas, et al
Philadelphia County CCP, April Term 2000; No.: 002621

Dear Steven:

I have reviewed the printout which you sent me of Mr. Morgan's Web site Lasiksucks4u. Although I strongly believe that this web site should be removed in its entirety, Dr. Nevyas has agreed to take no legal action against Mr. Morgan provided that the changes and deletions made to the web site as shown on the print out which you sent to me are not reinserted into the web site and provided further that Mr. Morgan makes no further attempts to defame my clients. We reaffirm the statements contained in my letter of July 30, 2003 detailing the defamatory material contained in the web site at that time, but agree that if there are no further attempts at defaming my clients we will take no legal action against Mr. Morgan for his past defamatory statements.

Very truly yours,

LEON W. SILVERMAN

cc: Herbert J. Nevyas M.D.

Exhibit 2

http://www.citizen.org/documents/nevyasmorganopinion.pdf

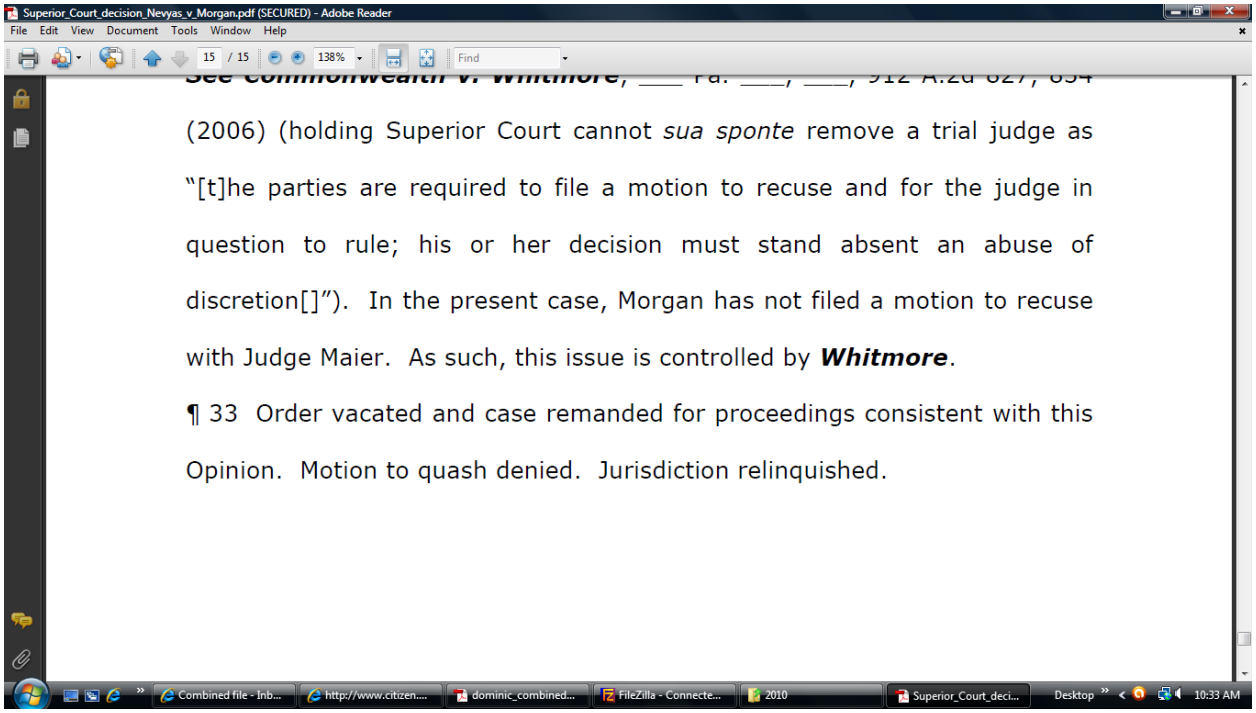


Exhibit 3

https://fjdefile.phila.gov/dockets/zk_fjd_public_qry_03.zp_dktrpt_frames?case_id=031100946

09-NOV-2009 11:12 AM	WSFFD - FINDING FOR DEFENDANT	ROGERS, PETER F		09-NOV-2009 11:13 AM
Docket Entry:	THE COURT FINDS THAT PLTFS ARE "LIMITED PURPOSE PUBLIC FIGURES" RELATIVE TO THE INSTANT DEFAMATION CASE. BY THE COURT ...ROGERS,J 10/14/09			

Exhibit 4

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 0004

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

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 the 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 the risk section of your informed consent document with additional [illegible] "You probably will not be able to see as well in situations

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 patients, because you have not provided adequate preliminary data to demonstrate safety of,

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 19 1997

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.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
US Food and Drug Administration Rm. 900 US Customhouse, 2nd and Chestnut Sts. Phila. PA 19106 (215) 597-4390	4/19,20, 23-30, 30, 5/1-4,7, 10/2001
	FEI NUMBER 2531320

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Dr. Herbert J. Nevyas MD

FIRM NAME	STREET ADDRESS
Medical Director	2 Bala Plaza, 333 City Ave
CITY, STATE AND ZIP CODE Bala Cynwyd PA 19004	TYPE OF ESTABLISHMENT INSPECTED Sponsor/Clinical Investigator

DURING AN INSPECTION OF YOUR FIRM I OBSERVED:

The following observations refer to the Investigational Device Exemption (Protocol # NEV-97-001) for the indicated study, "LASIK (Laser Intrastromal Keratomileusis) with an Excimer Laser in the Surgical Treatment of Refractive errors: Myopia with and without Astigmatism"

1. There was no documentation to show that the CI notified the IRB about all amendments, changes or significant deviations to the protocol [per IRB requirements] prior to implementation.

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

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

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

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE *(Print or Type)*	DATE ISSUED
	Ronald Stokes	Ronald Stokes	May 10, 2001

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 also obtain institutional review board (IRB) approval before implementing this change in your investigation (21 CFR 812.35(a)).

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

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administrat
9200 Corporate Boulevard
Rockville MD 20850

JAN 20 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.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 09 2001

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

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administratic
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.

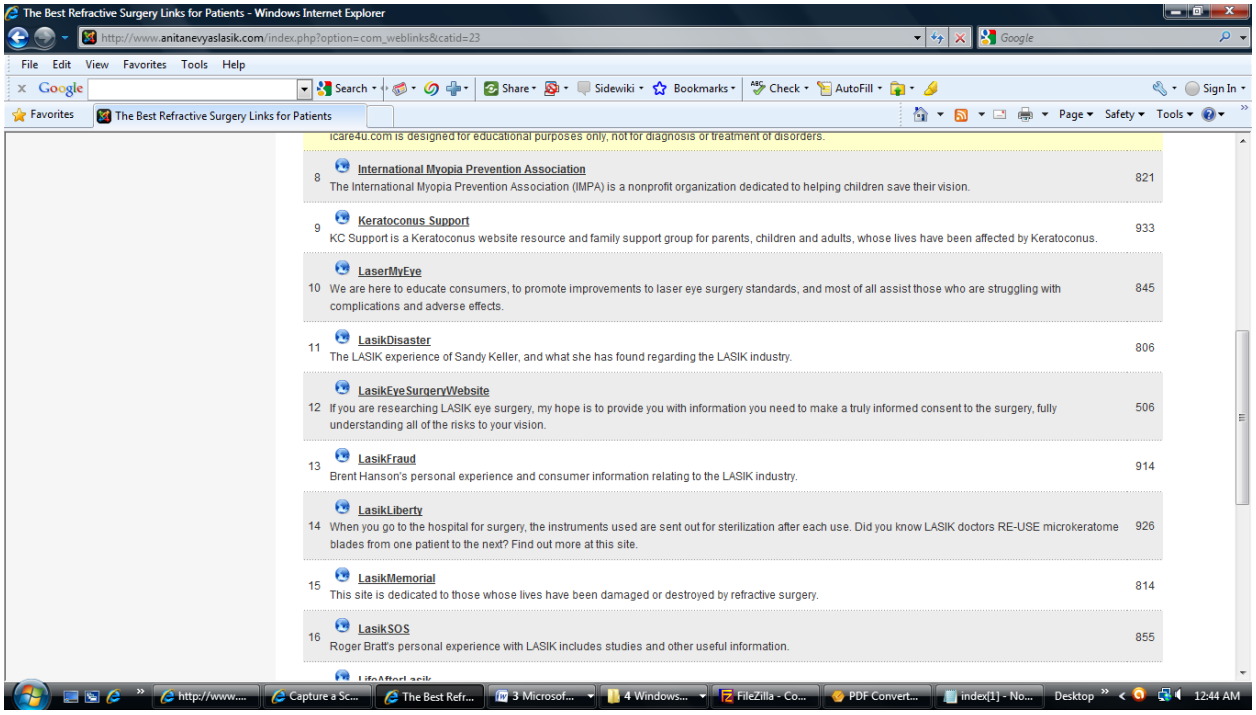
2. The provided Hazard Analysis and Test Data appear to be limited to the user-interface function of the software. Given all the functions of the software, please identify those that are either safety critical or safety-related (see the Checklist of Information Usually Submitted in an IDE for Refractive 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.

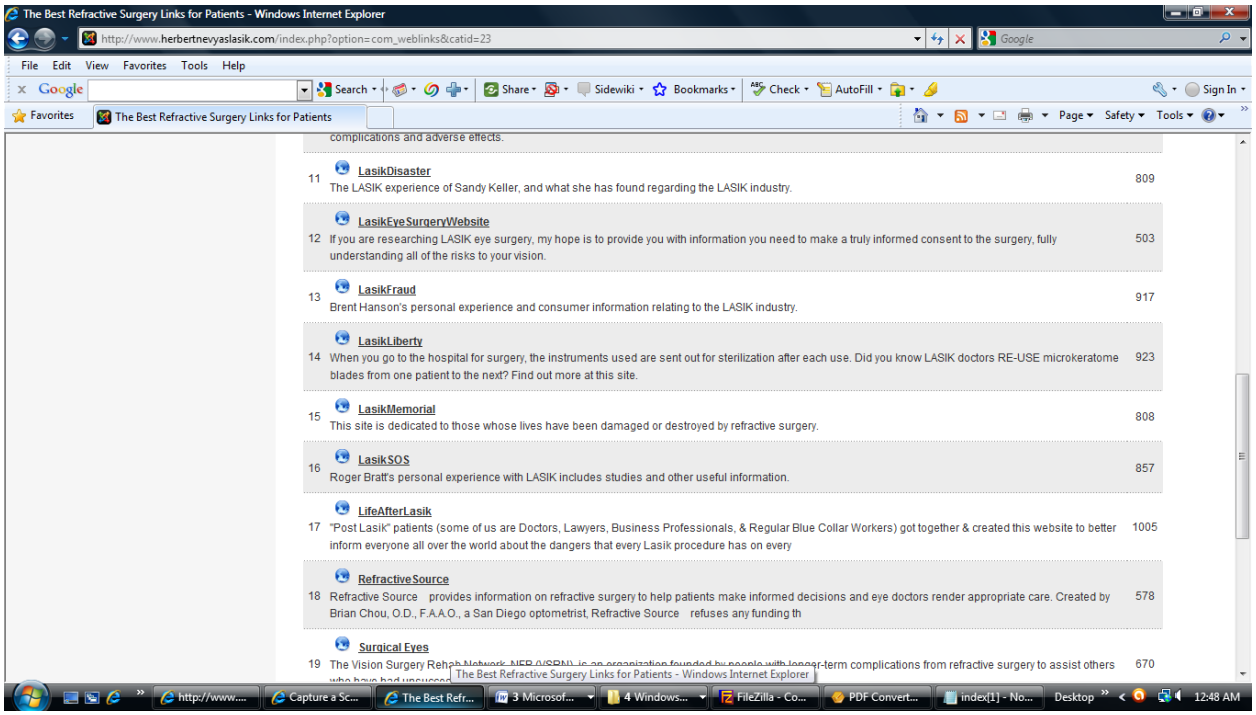
FDA 0 0074

Exhibit 5

http://www.anitanevyaslasik.com/index.php?option=com_weblinks&catid=23



http://www.herbertnevyaslasik.com/index.php?option=com_weblinks&catid=23



http://www.nevyaslasik.com/index.php?option=com_weblinks&catid=23

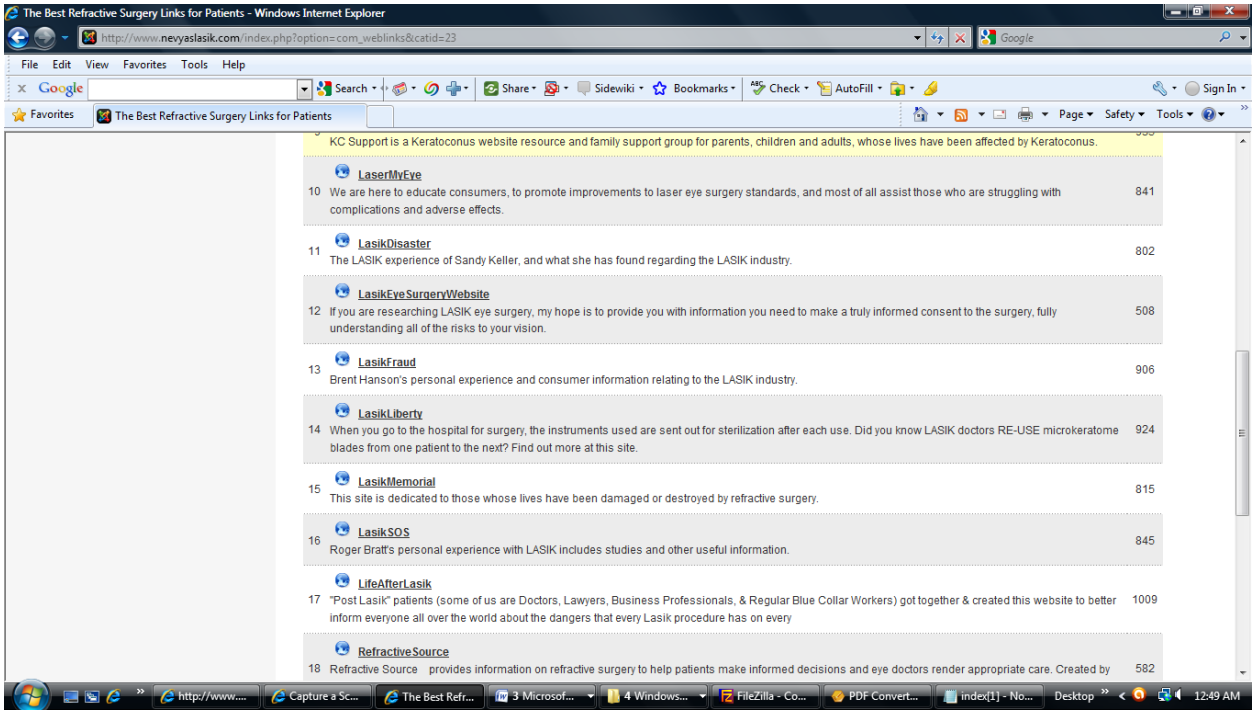


Exhibit 6

http://www.citizen.org/Page.aspx?pid=2306

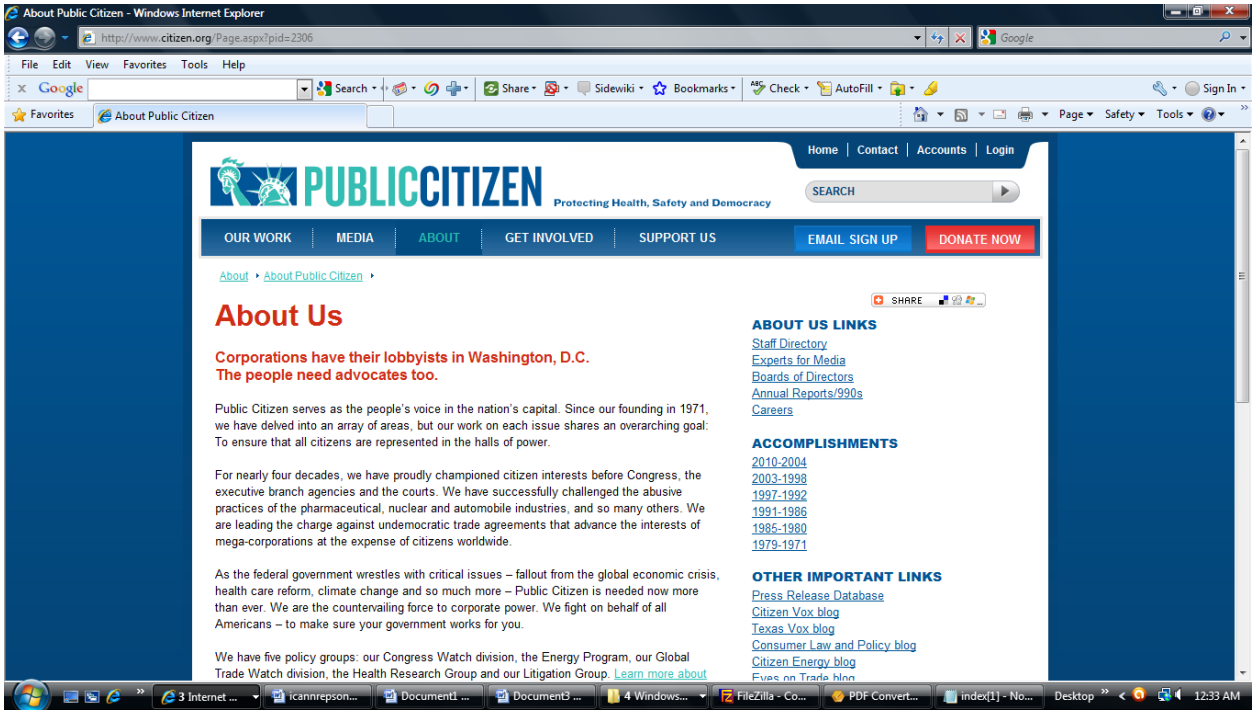


Exhibit 7

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

Mitchell E. Stein, M.D.
Retinal Disease, Glaucoma Medical and Surgical Ophthalmology

Vipin K. Goyal, M.D.
Corneal Surgery, Glaucoma and Refractive Surgery

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

Joshua M. Greene, M.D.
Vitreo-retinal Disease and Surgery

Avriram Shapiro, M.D., M.S.
Ophthalmic Plastic Surgery, Ocular Motility

Kenneth Morgenstern, M.D.
Cosmetic Oculoplastic Surgery, Facial and Reconstructive Surgery

July 31, 2007

Medical Review Unit
NJMVC
P. O. Box 173
Trenton, NJ 08666-0173

RE: Mr. Dominic Morgan
Pennsylvania Driver's License [redacted]

To Whom It May Concern:

I have serious concerns about the driving skills of Mr. Dominic Morgan (DOB [redacted] of [redacted] (alternate older address [redacted].

It is my understanding that Mr. Morgan maintains a valid New Jersey driver's license, even though he is no longer licensed in Pennsylvania. I examined Mr. Morgan from an ophthalmologic standpoint several years ago, and he reported vision as low as 20/200 in each eye when I last saw him. I know that he has been judged legally blind after an examination by Dr. John D. Dugan, Jr. in Voorhees, NJ, and that he is presently receiving Social Security Disability payments because of his legal blindness.

I think that Mr. Morgan should be re-evaluated by your impartial examiner and his license revoked if he does not measure up to the appropriate visual standard. I would not want to be responsible for allowing a legally blind driver to be on the highway.

Sincerely,

Herbert J. Nevyas, M.D.

HJN/ljs

To Whom It May Concern:

I hereby certify that this is a TRUE COPY

Chief Administrator

e-mail address:
nevyas@aol.com

Two Bala Plaza
333 City Avenue
Bala Cynwyd, PA 19004
610-668-2777
Fax 610-668-1509

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Fax 856-985-1191