MAY 1 2 2003

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
33033, 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
i 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 premarket notification submission to the Food and Drug Administration at least 90 days before he proposes to begin the introduction or delivery for introduction into interstate commerce for commercial distribution of a device intended 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 substantially 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 reclassified into class I or II.

(2) The device is being introduced into commercial distribution for the first time by a person required to register, 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 distribution or is reintroducing into commercial distribution, but that is about to be significantly changed or modified in design, components, method of manufacture, or intended use. The following constitute significant changes or modifications that require a premarket notification:

(i) A change or modification in the device that could significantly affect the safety or effectiveness of the device, e.g., a significant change or modification in design, material, chemical composition, energy source, or manufacturing 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 application 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 Administration.

(c) In addition to complying with the requirements of this part, owners or operators of device establishments that manufacture radiation-emitting electronic products, as defined in § 1000.3 of this chapter, shall comply with the reporting requirements of Part 1002 of this chapter.

§ 807.85 Exemption from premarket notification.

(a) A device is exempt from the premarket notification requirements of this subpart if the device intended for introduction into commercial distribution is not generally available in finished form for purchase and is not offered through labeling or advertising by the manufacturer, importer, or distributor thereof for commercial distribution, 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 premarket notification requirements of this subpart if:

(1) The device was in commercial distribution before May 28, 1976; or

(2) A premarket notification submission was filed by another person.

§ 807.87 Information required in a premarket notification submission.

Each premarket notification submission shall contain the following information:

(a) The device name, including both the trade or proprietary name and the common or usual name or classification 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 required to register to comply with the requirements of the act under section 514 for performance standards.

(e) Proposed labels, labeling, and advertisements sufficient to describe the device, its intended use, and the directions for its use. Where applicable, photographs 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 identification of similar products, materials, design considerations, energy expected to be used or delivered by the device, and a description of the operational principles of the device.

(g) Where a person required to register intends to introduce into commercial 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 submission must include appropriate supporting data to show that the manufacturer has considered what consequences and effects the change or modification or new use might have on the safety and effectiveness of the device.

(h) Any additional information regarding the device requested by the Commissioner that is necessary for the Commissioner to make a finding as to whether or not the device is substantially equivalent to a device in commercial distribution. A request for additional information will advise the owner or operator that there is insufficient 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 FANT

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. Nieuyas, MD
SPONSOR: Nieuyas 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: Following 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

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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

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

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

e-mail address:
nevyas@aol.com

☐ 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

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