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Via Federal Express

Food and Drug Administration
Rockville MD 20857

NOV 4 1997

WARNING LETTER

Wendell P. Wong, M.D.
Natural Sight Vision Center
3445 Pacific Coast Highway, Suite 200
Torrance, California 90505

Dear Dr. Wong:

During the period of September 9 -16, 1997, Natural Sight Vision Center was inspected by Ms. Omotunde O. Osunsanmi, an investigator from the Food and Drug Administration's (FDA) Los Angeles District Office. The purpose of the inspection was to determine whether your activities regarding your [REDACTED] of the [REDACTED] ([REDACTED]) for [REDACTED] treatment of [REDACTED] ([REDACTED]) [REDACTED] complied with applicable FDA regulations. Your [REDACTED] is a device as that term is defined in Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

Background

On March 28, 1997, FDA received your [REDACTED] application ([REDACTED]) for evaluation of the [REDACTED] for use in [REDACTED] treatment of [REDACTED] ([REDACTED]) [REDACTED]. In a letter dated April 25, 1997, FDA conditionally approved an [REDACTED] to treat [REDACTED] at [REDACTED] location. That conditional approval letter informed you that your [REDACTED] could begin once you submitted the name of your [REDACTED] ([REDACTED]) to FDA and received [REDACTED] approval. The April 25 letter also identified a number of deficiencies in your [REDACTED] application, which were to be corrected within 45 days. In a letter dated June 6, 1997, you responded to these deficiencies. By letter, dated July 8, 1997, FDA informed you that your [REDACTED] approval remained conditional because you had not adequately addressed deficiencies 2, 4, and 5 cited in the April 25 FDA letter.

On September 4, your consultant, Dr. [REDACTED], informed the Office of Device Evaluation (ODE), via a phone call to Dr. Morris Waxler, that you had disabled your [REDACTED] as part of your arrangement to acquire a [REDACTED].

The Office of Compliance (OC), through its Division of Bioresearch Monitoring (DBM), requested the September inspection of your facility. This inspection was conducted under a program designed to ensure that data and information contained in

applications for [REDACTED], [REDACTED], or [REDACTED] submissions are scientifically valid and accurate. Another objective of the program is to ensure that [REDACTED] are protected from undue hazard or risk during the course of the scientific [REDACTED].

Inspectional Findings

The inspection revealed that you had destroyed components of your [REDACTED], including the [REDACTED] manufactured by [REDACTED] (the [REDACTED]), the power supply, the [REDACTED] and stand, and the [REDACTED]. You provided FDA's investigator photographs of the destruction and a receipt for scrap materials from [REDACTED], dated August 29, 1997. You stated that the [REDACTED] had been terminated, with the last [REDACTED] procedure using the [REDACTED] occurring on August 7. The inspection also revealed that you have obtained a [REDACTED] Model [REDACTED].

In reviewing patient files from your [REDACTED], serious deviations from Title 21, Code of Federal Regulations, (21CFR), [REDACTED] - [REDACTED] and Part [REDACTED] were discovered. The deficiencies 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. Deviations noted include the following:

- [REDACTED] was performed on [REDACTED] subjects after April 25 without review and approval of the [REDACTED] by an [REDACTED]. The regulations pertaining to [REDACTED], 21 CFR [REDACTED], require that a [REDACTED] obtain [REDACTED] approval prior to initiating an [REDACTED]. See 21 CFR [REDACTED].
- The informed consent document used for [REDACTED] was not reviewed and approved by the [REDACTED]. It is the responsibility of the [REDACTED] to ensure that informed consent is obtained in accordance with FDA regulations for the Protection of [REDACTED]. 21 CFR Part [REDACTED] requires that informed consent be documented by the use of a written consent form approved by the [REDACTED].
- The informed consent used for the [REDACTED] does not contain all of the required elements. The required elements are delineated in 21 CFR [REDACTED].
- There is no evidence that any of your educational and promotional materials have been reviewed and approved by your [REDACTED]. Patient brochures and similar

educational materials describing [REDACTED] are seen as part of the informed consent and [REDACTED] selection process. They are a form of advertisement for the purpose of [REDACTED]. All materials must conform with 21 CFR [REDACTED], "Prohibition of [REDACTED] and other practices." Moreover, [REDACTED] review of these materials is necessary to ensure that the information provided to potential [REDACTED] is not misleading.

The deviations listed above are not intended to be an all-inclusive list of deficiencies. It is your responsibility as a [REDACTED] to ensure that your [REDACTED] is conducted in accordance with the signed agreement, the [REDACTED], and applicable FDA regulations for protecting the rights, safety, and welfare of [REDACTED] under your care.

For your information, although the information provided on your web site, at naturalsight.com, does not identify the [REDACTED] used, this information would be in violation of [REDACTED] if the only [REDACTED] available at your center to perform [REDACTED] were an [REDACTED] device. Because the procedures cannot be separated from the device being used, promotion of the procedures would violate the prohibition of [REDACTED] of [REDACTED] devices found in 21 CFR [REDACTED]. Moreover, all statements representing the procedures to be [REDACTED] would violate 21 CFR [REDACTED]). Information concerning [REDACTED] of [REDACTED] with an approved [REDACTED] is provided in the copy of an October 1996 letter to "Manufacturers and Users of [REDACTED] for [REDACTED]" which, Ms. Osunsanmi, the FDA investigator, supplied to you during the inspection.

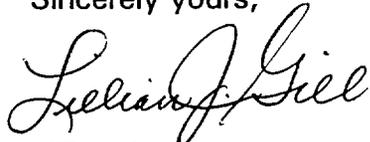
We acknowledge that you have destroyed key components of the [REDACTED] [REDACTED] and thus have terminated your [REDACTED] of this device. Please advise this office, in writing, within 15 working days of receipt of this letter, of the specific steps you have taken to prevent recurrence in future [REDACTED] of violations similar to those listed above. For your information, copies of 21 CFR Parts [REDACTED] and [REDACTED] are enclosed. Your response should include a certification that you will not use the [REDACTED] components you did not destroy, mainly the computer used to operate the [REDACTED], along with its [REDACTED] algorithms and software data base, in the assembly of a [REDACTED] to treat patients, unless an approved [REDACTED] or [REDACTED] is in effect for the resulting device. Please send your response to the Food and Drug Administration, Center for Devices and Radiological Health, Office of Compliance, Division of Bioresearch Monitoring, Program Enforcement Branch II (HFZ-312), 2098 Gaither Road, Rockville, Maryland 20850, Attention: Jean Toth-Allen, Ph.D.

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A copy of this letter has been forwarded to our Los Angeles District Office, 19900 MacArthur Boulevard, Suite 300, Irvine, California 92715. We request that a copy of your response be sent to that office.

If you have any questions, you may contact Jean Toth-Allen at (301) 594-4723, ext. 141.

Sincerely yours,

A handwritten signature in cursive script that reads "Lillian J. Gill". The signature is written in black ink and is positioned above the printed name and title.

Lillian J. Gill

Director

Office of Compliance

Center for Devices and Radiological
Health

Enclosures