DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

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May 11, 2001

NOTICE OF INITIATION OF DISQUALIFICATION PROCEEDINGS AND OPPORTUNITY TO EXPLAIN

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Leon C. LaHaye, M.D.
LaHaye Center for Advanced Eye Care
201 Rue Iberville, Suite 800
Lafayette, Louisiana 70508

Dear Dr. LaHaye:

Between March 14, 2001, and April 18, 2001, Food and Drug Administration (FDA) investigators, Ms. Dana Daigle, Ms. Barbara Wright, and Mr. Francis Guidry, conducted an inspection of the following clinical trials for which you are the sponsor/clinical investigator:

1. Use of the [redacted]

2. Use of the [redacted]

This inspection was conducted as part of the FDA's Bioresearch Monitoring Program that includes inspections designed to monitor the conduct of research involving investigational products.

FDA's New Orleans District Office provided us a copy of a letter dated April 27, 2001, submitted on your behalf by Michael D. Skinner of the law firm *Onebane, Bernard, Torian, Diaz, McNamara & Abell* and located in Lafayette, Louisiana, in reference to the inspection.

Based on our evaluation of information obtained by the Agency, we believe that you have repeatedly and/or deliberately violated regulations governing the proper conduct of clinical studies involving investigational products, as published under Title 21, Code of Federal Regulations (21 CFR), Part 812, Investigational Device Exemptions (copy enclosed), and repeatedly and/or deliberately submitted false information.

This letter provides you with written notice of the matters under complaint and initiates an administrative proceeding, described below, to determine whether you should be disqualified from receiving investigational products as set forth under 21 CFR 812.119.

A listing of the violations follows. The applicable provisions of 21 CFR Part 812 are cited for each violation.

1. **You failed to conduct the investigational studies according to conditions of approval imposed by the FDA, in violation of 21 CFR 812.110(b).**

   Your [redacted] FDA investigational findings revealed that between October 29, 1997, and the time of the inspection you treated over 2,900 eyes with your [redacted]. The inspectional report also notes that you admitted to treating patients with your [redacted] outside of the study protocols.

2. **You failed to submit accurate and complete reports, in violation of 21 CFR 812.150.**

   a. You failed to include in your monthly reports all eyes treated with your [redacted]. A condition of your [redacted] requires that you submit monthly reports to the FDA as to the number of eyes treated with your [redacted].

   b. You failed to report all eyes treated with your [redacted] in your regular progress reports as a clinical investigator to your reviewing institutional review board (IRB).

3. **You failed to obtain IRB approval for [redacted] prior to treating subjects, in violation of 21 CFR 812.110(a).**

   According to investigational findings, at least 226 eyes were treated with your [redacted]

4. **You failed to maintain accurate and complete records of eyes treated with the [redacted] device as required by 21 CFR 812.140(a)(3).**

   a. Patient charts for eyes treated "off-protocol" with the [redacted] contain false information. These charts indicate that the Summit laser was used but contain copies of [redacted] algorithm print-outs from the [redacted] actually used for the treatment.

   b. Patient charts for some of the eyes treated between July 14, 1999, and April 26, 2000, contain copies of print-outs for both the [redacted] and [redacted] algorithms for the indicated treatment. There is no information within these charts to indicate which algorithm was actually used for the treatment.

   c. Patient charts for all eyes treated with the [redacted] contain a signed copy of the informed consent document used for the investigational study, whether the eye was treated as part of the study or "off-protocol."

5. **You commercialized your [redacted] in violation of 21 CFR 812.7.**

   You advertised and used your [redacted] as if it was an approved medical device. Both a patient brochure and a descriptive video distributed to patients considering refractive surgery contain statements purporting that the [redacted] is safe and effective for the indicated uses and contain no statement that the [redacted]

This letter is not intended to be an all-inclusive list of deficiencies with your clinical studies of the [redacted] It is your responsibility to ensure adherence to each requirement of the law and relevant regulations.

On the basis of the violations listed above, the FDA asserts that you have repeatedly and/or deliberately failed to comply with the cited regulations and repeatedly and/or deliberately submitted false information and it proposes that you be disqualified as a clinical investigator. You may reply to the issues stated above, including an explanation of why you should remain eligible to receive investigational products and not be disqualified as a clinical investigator, in a written response or at an informal conference in my office. This procedure is provided for by regulation 21 CFR 812.119(a).

Within fifteen (15) days of receipt of this letter, write or call Viola Sellman at (301) 594-4723, extension 127 to arrange a conference time or to indicate your intent to respond in writing to this letter. Your written response must be forwarded within thirty (30) days of receipt of this letter. Your reply should be sent to

Viola Sellman
Chief
Program Enforcement Branch II, HFZ-312
Division of Bioresearch Monitoring
Office of Compliance
Center for Devices and Radiological Health
Food and Drug Administration
2098 Gaither Road,
Rockville, Maryland 20850

Should you request an informal conference, we ask that you provide us with a full and complete explanation of the violations listed above. You should bring with you all pertinent documents and you may be accompanied by a representative of your choosing. Although the conference is informal, a transcript of the conference will be prepared. If you choose to proceed in this manner, we plan to hold such a conference within 30 days of your request.

At any time during this administrative process, you may enter into a consent agreement with the FDA regarding your future use of investigational products. Such an agreement would terminate this disqualification proceeding. Enclosed you will find a proposed agreement between you and the FDA.

The Center for Devices and Radiological Health (CDRH) will carefully consider any oral or written response. If your explanation is accepted by CDRH, the disqualification process will be terminated. If your written or oral responses to our allegations are unsatisfactory, or we cannot come to terms on a consent agreement, or you do not respond to this notice, you will be offered a regulatory hearing before the FDA, pursuant to 21 CFR Part 16 (copy enclosed) and 21 CFR 812.119. Before such a hearing, the FDA will provide you notice of the matters to be considered, including a comprehensive statement of the basis for the decision or action taken or proposed, and a general summary of the information that will be presented by the FDA in support of the decision or action. A presiding officer free from bias or prejudice and who has not participated in this matter will conduct the hearing. Such a hearing will determine whether or not you will remain entitled to receive investigational products.

You should be aware that neither entry into a consent agreement nor pursuit of a hearing precludes the possibility of a corollary judicial proceeding or administrative remedy concerning these violations.

Sincerely yours,

Charma A. Konnor, R.Ph., RAC
Director
Division of Bioresearch Monitoring
Office of Compliance
Center for Devices and
Radiological Health

Enclosures

cc:

[redacted]