DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

JAN - 8 2002

NOTICE OF OPPORTUNITY FOR HEARING (NOOH)

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Leon C. LaHaye, M.D.
c/o Peter S. Reichertz
Arent, Fox, Kintner, Plotkin, & Kahn, PLLC
1050 Connecticut Avenue, NW
Washington, D.C. 20036-5339

Dear Dr. LaHaye:

The Center for Devices and Radiological Health (CDRH), Food and Drug Administration (FDA), has information indicating that you repeatedly or deliberately violated Federal regulations, and repeatedly or deliberately submitted false information in required reports in your capacity as a sponsor/clinical investigator in clinical trials with an investigational medical device, specifically, the [redacted] The violations provide the basis for withdrawal of your eligibility as a clinical investigator to receive investigational devices.

Pursuant to section 812.119 of Title 21, Code of Federal Regulations (21 CFR), CDRH informed you, by letter dated May 11, 2001, of the specific matters complained of and offered you an opportunity to respond to them in writing or at an informal conference. That same letter gave you the option of entering into a consent agreement that was enclosed, thereby terminating any administrative proceeding against you. In a letter dated June 14, 2001, your attorney, Peter S. Reichertz, responded on your behalf with a written explanation and proposed changes to the consent agreement. CDRH informed you, by letter dated August 1, 2001, that it accepted some of your proposed changes to the consent agreement, but rejected most other changes. CDRH enclosed a revised consent agreement and again gave you the option of entering into the agreement. You did not respond to the CDRH August 1, 2001, letter.

CDRH has concluded that your written explanation of June 14 is unacceptable because it fails to adequately address the violations. Accordingly, you are being offered an opportunity for a regulatory hearing pursuant to 21 CFR part 16 and 812.119, on the question of whether you are entitled to receive investigational devices. You have the right to be advised and represented by counsel at all times. Any regulatory hearing on this matter will be governed by the regulations in 21 CFR part 16 and the agency's guidelines on electronic media coverage of administrative proceedings, 21 CFR part 10, Subpart C. Enclosed you will find

copies of these regulations. A listing of the specific violations follows. These are the matters that will be considered at the regulatory hearing. Applicable provisions of the CFR 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 investigational device exemption (IDE) is for treatment of 754 eyes under protocol 1 and 50 eyes under protocol 2. However, between October 29, 1997, and March 14, 2001, you treated over 2,900 eyes with your investigational [redacted] During the inspection initiated on March 14, 2001, you admitted to treating more patients with your investigational [redacted] than permitted under 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 listings of all eyes treated with your investigational [redacted] A condition of your IDE requires that you submit monthly reports to the FDA, including the number of eyes treated with your investigational [redacted]

   b. You failed to report all eyes treated with your investigational [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 protocol 2 prior to treating subjects, in violation of 21 CFR 812.110(a).**

   You treated at least 226 eyes with your investigational [redacted] using the [redacted] specific to protocol 2 [redacted] between July 14, 1999, and April 26, 2000, the date of IRB approval of this protocol.

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

   a. Patient charts for eyes treated "off-protocol" with the investigational [redacted] contain false information. These charts indicate that the [redacted] was used but contain copies of [redacted] print-outs from the investigational [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 protocol 1 and protocol 2 [redacted] for the indicated treatment. There is no information

within these charts to indicate which [redacted] was actually used for the treatment.

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

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

Your request for a hearing must be made, in writing, within ten (10) business days of receipt of this letter and should be directed to James F. McCormack, Ph.D., Coordinator, Bioresearch Monitoring Program, Office of Enforcement, Division of Compliance Policy (HFC-230), 5600 Fishers Lane, Rockville, Maryland 20857, Telephone: (301) 827-0425, Facsimile: (301) 827-0482. If no response to this letter is received by that time, you will be deemed to have waived any right to a regulatory hearing, and a decision in this matter will be made based on the facts available to the agency. No hearing will be held.

A request for a hearing may not rest upon mere allegations or denials but must present specific facts showing that there is a genuine and substantial issue of fact that warrants a hearing. Pursuant to 21 CFR 16.26, a request for a hearing may be denied, in whole or in part, if the Commissioner or his delegate determines that no genuine and substantial issue of fact had been raised by the material submitted. A hearing will not be granted on issues of policy or law. Written notice of a determination of summary judgment will be provided explaining the reasons for denial of the hearing.

If you wish to respond but do not desire a hearing, you should contact Dr. McCormack within the time period specified above and send a written response containing your reply. The letter should state that you waive your right to a hearing and that you want a decision on the matter to be based on your written response and other information available to the agency.

CDRH's offer to enter into the consent agreement enclosed in its August 1, 2001, letter remains available. Entering into a consent agreement would terminate the administrative procedures, but would not preclude the possibility of a corollary judicial proceeding.

No final decision by FDA has been made at this time on your eligibility to continue to use investigational devices. Moreover, there will be no prejudgment of this matter if you decline to enter into a consent agreement and decide instead either to request a regulatory hearing or to request that the decision be based on information currently available to the agency.

Please inform Dr. McCormack within ten (10) days of whether you wish to request a hearing or to have this matter resolved by consent agreement or information available to the agency.

Sincerely,

Dennis E. Baker
Associate Commissioner for
Regulatory Affairs

Enclosures
21 CFR Part 10, Subpart C
21 CFR Part 16
21 CFR Part 812