DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

JUN 18 2002

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

**Notice of Disqualification of Entitlement to Receive Investigational Devices**

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

Dear Dr. LaHaye:

On January 8, 2002, the United States Food and Drug Administration (FDA) sent you, through your attorney Mr. Peter S. Reichertz, a Notice of Opportunity for a Hearing (NOOH) (enclosed) pursuant to sections 16.22 and 812.119 of Title 21, Code of the Federal Regulations (CFR), to determine whether you would remain entitled to receive investigational devices. On January 31, 2002, your attorney Mr. Charles J. Boudreax, Jr., responded to the NOOH on your behalf (enclosed), informing the FDA that you waived your right to a hearing and desired a decision on the matter to be based on your written explanations contained in your previous written responses, your January 31, 2002 letter to FDA, and other information available to the agency.

Prior to the issuance of the NOOH, the Center for Devices and Radiological Health (CDRH) informed you, by letter titled "Notice of Initiation of Disqualification Proceedings and Opportunity to Explain" (NIDPOE), 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 pursuant to 21 CFR 812.119. The NIDPOE also offered you an opportunity to enter into a consent agreement with FDA, which would have terminated the administrative disqualification proceeding.

In response to the NIDPOE, your attorney, Mr. Reichertz, submitted a written explanation addressing the matters under complaint. CDRH reviewed the explanation and concluded that the explanation failed to address the violations stated in the NIDPOE. Accordingly, as indicated above, on January 8, 2002, you were offered an opportunity for a regulatory hearing.

On the basis of all information available to the FDA, I have determined that you repeatedly and deliberately violated FDA regulations governing the conduct of clinical investigators and the use of investigational devices. Furthermore, I have concluded that you repeatedly and deliberately submitted false information in

required reports for studies of investigational devices that are subject to section 520 of the Federal Food, Drug, and Cosmetic Act. You committed the violations in your capacity as the sponsor/investigator for the two studies of an investigational [redacted] under an investigational device exemption, including Protocol 1 [redacted]: Use of the LaHaye Model [redacted] System for [redacted] treatment of [redacted] and [redacted] of eyes treated with the [redacted]; and Protocol 2 [redacted]: Use of the LaHaye Model [redacted] for [redacted].

Specifically:

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] clearly indicates it was limited to the treatment of 754 eyes under protocol 1 and 50 eyes under protocol 2. However, your records show that between October 29, 1997, and March 14, 2001, you treated over 2,900 eyes with the investigational [redacted]. During the inspection initiated on March 14, 2001, you admitted to the FDA investigator that you treated more patients with the 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 the investigational [redacted]. A condition of the [redacted] requires that you submit monthly reports to the FDA, including the number of eyes treated with the investigational [redacted].

   b. You failed to report all eyes treated with the investigational [redacted] in your regular required progress reports as a clinical investigator to the 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).**

   Patient charts clearly show that you treated at least 226 eyes with the 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. Regulations require the investigator maintain accurate, complete, and current records of each subject's exposure to the device. Your 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] 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, prior to IRB approval, contain copies of print-outs for both the protocol 1 and protocol 2 [redacted]. There is no information within these charts to indicate which [redacted] was actually used.

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

   You advertised and used the investigational [redacted] as if it was an approved medical device. FDA obtained a patient brochure and a descriptive video distributed to patients considering [redacted] that contain statements that the [redacted] is safe and effective for the [redacted]. These promotional materials fail to explain that the [redacted] is an investigational device.

**In accordance with 21 CFR Parts 16 and 812, you are hereby advised that you are no longer entitled to receive investigational devices. All such articles in your possession should be promptly dismantled and disposed, or returned to their suppliers.**

The FDA will make this notice available to interested parties under the Freedom of Information Act (FOIA). Your name will also be added to the list of clinical investigators who have been disqualified or totally restricted from being eligible to receive investigational articles. This list is available under FOIA and is posted on the FDA's internet site.

Sincerely,

Lester M. Crawford, D.V.M, Ph.D.
Deputy Commissioner

Enclosures