DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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Food and Drug Administration
Center for Devices and
Radiological Health
2098 Gaither Road
Rockville, MD 20850

OCT 4 2004

Via Federal Express

WARNING LETTER

Neil Camera, President
Laser Therapeutics, Inc.
101 Waterside Drive
Centerville, MA 02632

Dear Mr. Camera:

This Warning Letter informs you of the objectionable conditions found during the Food and Drug Administration (FDA) inspection conducted at your sponsor site. This letter also discusses your verbal and your written reply dated June 20, 2004, to the Form FDA 483 noted violations and requests that you provide a written reply to this letter as well as implement prompt corrective actions. Ms. Sandra P. White, an investigator from the FDA's New England District Office conducted the inspection from April 5 through April 15, 2004. The purpose of the inspection was to determine whether your activities and procedures as a sponsor and monitor for clinical studies of the MediCom a.s. Low Level Laser complied with applicable FDA regulations. The MediCom a.s. Low Level Laser is a device as that term is defined under Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act) [21 U.S.C. 321(h)].

This inspection was conducted under a program designed to ensure that data and information contained in Investigational Device Exemption (IDE) applications, Premarket Approval (PMA) applications, and Premarket Notification [510(k)] submissions are scientifically valid and accurate. The program is also designed to ensure that human subjects are protected from undue hazard or risk during the course of scientific investigations.

Our review of the inspection report prepared by the New England District Office revealed serious violations of Title 21, Code of Federal Regulations (21 CFR), Part 812 - Investigational Device Exemptions. At the conclusion of the inspection, Ms. White presented and discussed with you the observations listed on the Form FDA 483 "Inspectional Observations." In your written response, you appear to have adequately addressed several of the observations identified. However, the following violations require further explanation.

Failure to establish written procedures for monitoring the investigation (21 CFR 812.25); Failure to ensure proper monitoring of the investigational study (21 CFR 812.40)

Pursuant to 21 CFR 812.25, a sponsor is responsible for providing within the investigational plan written procedures for monitoring the investigation. Pursuant to 21

CFR 812.40, a sponsor must ensure proper monitoring of the investigation You failed to adhere to these requirements, as explained below.

You have no established procedures or guidelines for monitoring any of your ongoing protocols. In your written response you acknowledge that you do not have established monitoring procedures and that you are in the process of formalizing such procedures. Having not seen or reviewed the procedures, FDA cannot determine their adequacy. However, establishing and following complete monitoring procedures should assist you in avoiding recurrence of the problems noted during the inspection.

There is no evidence of having ensured proper monitoring of any of the study sites. You have no documentation of monitoring site visits. When asked about monitoring during the inspection, you stated that on-site visits were not always documented.

Failure to maintain accurate, complete, and current records relating to an investigation. 21 CFR 812.140(b).

A sponsor must maintain accurate, complete, and current records of all correspondence with another sponsor, a monitor, an investigator, or an IRB, including required reports. (21 CFR 812.140(b)(1)). A sponsor must also maintain accurate, complete and current records for any nonsignficant risk study that include the name and intended use of the device and the objectives of the investigation, the name and address of each investigator, and the name and address of each IRB that has reviewed the investigation. (21 CFR 812.140(b)(4)). These records must be maintained for at least two years after the date on which the investigation is terminated or completed. (21 CFR 812.140(d)).

You violated these requirements. For example:

With respect to protocol [redacted] submitted to the [redacted] under study number [redacted] and protocol [redacted] submitted twice to the [redacted] under numbers [redacted] and [redacted] some of your electronic records were lost due to destruction by a computer virus and there is no documentation of any hard copy records maintained. Consequently, documentation of these studies is incomplete.

With regard to protocol [redacted] study # [redacted], you were unable to provide the original study protocol as submitted to the reviewing IRB, a copy of your submission request to that IRB, or the IRB's approval letter. You claim to have formally terminated protocol [redacted] with the [redacted] on June 28, 2003, and have no record of any communication between the [redacted] and you following that date. Although you indicated to the investigator that you had not received any contact or correspondence from the [redacted] after that date, numerous letters from [redacted] had been sent to you regarding studies over which the [redacted] was involved, including letters of August 4, 2003, informing you of the termination of study [redacted] (enclosed); and a certified letter from Covington & Burling (representing [redacted] dated February 11, 2004, (enclosed) requesting that you cease distribution of [redacted] informed consent forms and referencing the termination of study [redacted]

You also have no documentation that after the termination of your relationship with [redacted] as the reviewing IRB for protocol [redacted] that you informed the clinical investigator(s) involved of this change or instructed them how to proceed given the absence of IRB approval.

Furthermore, in a letter dated February 5, 2005 (sic), you responded to an FDA Warning Letter dated January 12, 2004 to Medicom a.s., identifying Laser Therapeutics as the registered agent of that laser manufacturer. In that letter, you state that you at that time had three ongoing "IRB sponsored clinical trials," not specifically identified, and indicate that one of these trials was being overseen by the [redacted] Yet you have no records of correspondence with the [redacted] with respect to **any** study after June 28, 2003.

In addition, for any study of a nonsignificant risk device, pursuant to 21 CFR 812.140(b)(4), you should have records clearly identifying for each study the intended use of the device and study objectives, and the name and address of all IRBs that have reviewed the study. You do not appear to have such clear records, and have no record indicating the [redacted] as the current IRB for any ongoing study, despite your representations to FDA in the February 5, "2005", letter.

With respect to protocol [redacted] your records are incomplete in many respects. You have claimed that Dr. [redacted] the principal investigator of the study, was also the study sponsor. However, the limited records you maintain include the IRB Study Submission Form for study [redacted] dated 6/26/2002, which is more recent than any other record of IRB submission in your files for this study, and which identifies Laser Therapeutics as the sponsor of the study. There is no record of transfer, discontinuation, or final report of the study at this site by Laser Therapeutics and likewise there is no record of disposition of the devices under investigation following dissolution of the business relationship at this site. Lack of any documentation of termination of the study at this site suggests that the study remains your responsibility as the sponsor. Your records regarding all aspects of this study are extremely limited, although you indicated to the FDA investigator that the study is ongoing. This is particularly troubling as this protocol was originally approved by the [redacted] and as indicated above, the [redacted] maintains that it no longer oversees any ongoing studies of Laser Therapeutics' devices.

Please explain the foregoing record keeping deficiencies and in particular, why you have no documentation of correspondence with the [redacted] subsequent to June 2003. Explain procedures and activities you will undertake to assure in the future that all records are maintained.

Within 15 working days after receiving this letter please provide written documentation of the specific steps you have taken or will take to correct these violations and prevent the recurrence of similar violations in current and future studies. Any submitted corrective action plan must include projected completion dates for each action to be accomplished. Failure to respond to this letter and take appropriate corrective action could result in the FDA taking regulatory action without further notice to you.

Send your response to:

Food and Drug Administration
Center for Devices and Radiological Health
Office of Compliance
Division of Bioresearch Monitoring
Program Enforcement Branch II (HFZ-312)
2094 Gaither Road
Rockville, Maryland 20850
Attention: Mr. G. Levering Keely, BSN, MPA,
Consumer Safety Officer.

We are also sending a copy of this letter to FDA's New England District Office, One Montvale Ave., 4th Floor, Stoneham, MA 02180. We request that you also send a copy of your response to that office.

The above listed violations are not intended to be an all-inclusive list of violations that may exist in your clinical studies. It is your responsibility as the sponsor to ensure adherence to each applicable requirement of the Act and FDA regulations. In addition to responding to this Warning Letter, we request that you meet with FDA to clarify the conflicting information about several of your studies that results from statements in your February 5, "2005", letter to FDA, the information collected during the April 2004 FDA inspection, and from the correspondence from the [redacted] to your company. You may schedule this meeting by calling Mr. Levering G. Keely at (240) 236-0125.

Sincerely yours,

Timothy A. Ulatowski
Director
Office of Compliance
Center for Devices and
Radiological Health

Attachments:
[redacted] Letter dated August 4, 2003
Letter dated February 11, 2004