



JUN 24

WARNING LETTER
Via Federal Express

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

Cheryl Jones Jaye, M.D.
LifeWorks Wellness Center, Inc.
301 Turner Street
Clearwater, Florida 33756

Dear Dr. Jaye:

The purpose of this Warning Letter is to inform you of objectionable conditions found during a Food and Drug Administration (FDA) inspection conducted at your clinical site and to request a prompt reply. The inspection took place during the period of March 19 through 28, 2003, and was conducted by Mr. Ernest A. Clausnitzer and Ms. Joan S. Norton, investigators from FDA's Florida District Office. The purpose of the inspection was to determine if your activities as a clinical investigator in [REDACTED] study to evaluate the use of the [REDACTED] [REDACTED] comply with applicable FDA regulations. The [REDACTED] is a device as that term is defined in Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. § 321(h).

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

Our review of the inspection report submitted by the district office revealed serious violations of requirements of Title 21, Code of Federal Regulations (21 CFR), Part 812 - Investigational Device Exemptions, and Part 50 - Protection of Human Subjects, and Section 520(g) of the Act. You received a Form FDA 483, "Inspectional Observations," at the conclusion of the inspection that listed the deviations which were discussed with you. The deviations noted on the Form FDA 483 and our subsequent review of the inspection report are discussed below.

Failure to obtain signed and dated informed consent documents from all individuals treated with the investigational device prior to treatment (21 CFR 812.100 and 50.20).

The investigational report notes that at least four (4) patients of your Center were treated with the [REDACTED] outside of the study and that the device was also used on you and one of your study coordinators. At least eight (8) additional patients received a complimentary [REDACTED] treatment and then chose not to continue such treatments. In addition, you could not locate informed consent documents for at least six (6) study subjects and at least five (5) subjects received one or more [REDACTED]

█ treatments prior to signing an informed consent document. An investigator is required by 21 CFR 812.100 to ensure that informed consent is obtained according to 21 CFR Part 50. According to 21 CFR 50.20, no investigator may involve a human being as a subject in research unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative.

Treatment of study subjects during the period of time the study lacked institutional review board (IRB) approval (21 CFR 812.110(a)).

The inspectional report contains a copy of a June 7, 2002, letter from the █ IRB informing your site that the IRB had withdrawn approval for the study; the letter stated that all research activity with the investigational device must cease. The █ IRB did not approve the study until September 24, 2002. Your Center treated at least 50 subjects during the time the study lacked IRB approval. To participate in investigational device studies, study sites must obtain and maintain IRB approval.

Failure to conduct the study in accordance with the investigational plan (21 CFR 812.100 and 812.110(b)).

Of the 29 subject files that received a comprehensive review, five (5) files contained evidence that the subject did not meet the inclusion/exclusion criteria. Review of approximately 150 subject files revealed at least 25 informed consent documents that lacked a witness signature and date as well as a number of consent documents that lacked a principal investigator signature. Your site also lacks a master subject log, maintenance of which is required in the study protocol. Moreover, according to the protocol, the study is designed to evaluate the effectiveness of █ █. Inspectional findings revealed subjects who received █ treatments for █ and subjects who were not indicated as █. An investigator is required to conduct an investigation in accordance with the investigational plan.

Failure to maintain accurate, complete, and current subject records (21 CFR 812.140(a)(3)).

A review of approximately 150 subject files revealed that case report forms (CRFs) were routinely incomplete and/or not properly maintained. Deficiencies noted include: failure to record pre- and post-treatment █ and █; failure to record vital signs; failure to record triglyceride test results; failure to document required follow-up activities; failure to record █ settings; use of a single CRF to record multiple treatments; and use of a CRF that was copied with previously entered pain assessments, vital signs, and █ settings. An investigator is required to maintain accurate, complete, and current records of each subject's case history and exposure to the device.

Failure to use the correct informed consent document for study subjects (21 CFR 50.27(a)).

The inspection revealed that at least five (5) subjects signed the initial informed consent document approved by [REDACTED] IRB after the [REDACTED] IRB had approved the study and revised the informed consent document. Informed consent must be documented by use of the written consent form approved by the IRB.

In addition to the deviations noted in the Form FDA 483, our review of the inspection report revealed that access to the [REDACTED] is not restricted, allowing the potential for unauthorized use. Please note, that according to 21 CFR 812.110(c), an investigator is responsible for ensuring the proper use of an investigational device.

Also, investigators are required by 21 CFR 812.150(a)(3) to submit progress reports to the sponsor at regular intervals, but in no event less often than yearly. The inspection report notes that there is no evidence that information about the study was ever reported to [REDACTED].

The deviations listed above are not intended to be an all-inclusive list of deficiencies that may exist in your clinical study. It is your responsibility as a clinical investigator to ensure that an investigation is conducted according to the signed agreement, the investigational plan, and applicable FDA regulations.

In addition to the deviations discussed above, we note that the informational brochure distributed to recruit potential [REDACTED] subjects at your clinic, entitled "[REDACTED] at LifeWorks Wellness Center," was not reviewed and approved by the IRB before distribution to potential study subjects. FDA guidance recommends that the IRB should review the methods and materials that investigators propose to use to recruit subjects before such materials are distributed. See <http://www.fda.gov/oc/ohrt/irbs/> (click on Recruiting Study Subjects).

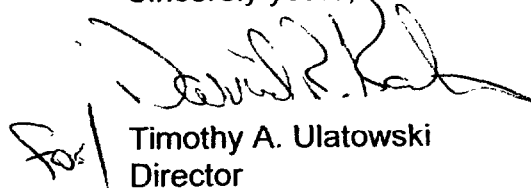
Please inform us, in writing, within 15 working days of receipt of this letter, of the corrective actions you have taken or plan to take to ensure that the deviations noted are not repeated in this study or future studies. Please send this information to the Food and Drug Administration, Center for Devices 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. Failure to respond could result in regulatory action without further notice, including the initiation of investigator disqualification procedures.

A copy of this letter has been sent to FDA's Florida District Office, 555 Winderley Place, Suite 200, Maitland, Florida 32751. We request that a copy of your response also be sent to that office.

Page 4 – Cheryl Jones Jaye, M.D.

If you have any questions, feel free to contact Dr. Toth-Allen at (301) 594-4723, ext. 141.

Sincerely yours,



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

cc: (purged copies)

