



JUN 17 2006

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

Via Federal Express

WARNING LETTER

Michael R. Piazza, M.D.
1022 Jeffords Street, Suite C
Clearwater, Florida 34616

Dear Dr. Piazza:

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 your prompt reply informing us of your corrective actions. During the period of February 14 through February 28, 2003, Ms. Virginia L. Meeks, an investigator from the FDA's Florida District Office visited you. The purpose of that visit was to conduct an inspection to determine whether your activities and procedures as a clinical investigator for the investigational study of the [REDACTED] sponsored by [REDACTED] [REDACTED] complied 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).

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 (PMA), or Premarket Notification (510(k)) submissions 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 Florida District Office revealed serious violations 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. At the conclusion of the inspection, Ms. Meeks presented and discussed with you the observations listed on the Form FDA 483 “Inspectional Observations.” Also present were [REDACTED] and [REDACTED] former [REDACTED]

The deviations noted on the Form FDA 483 and our subsequent review of the inspection report are discussed below. The deviations noted include:

Failure to obtain informed consent (21 CFR Part 50 and 21 CFR 812.100).

A review of all 10 patient records at your study site revealed the following:

- You failed to obtain written informed consent prior to surgery for one patient. The patient signed the informed consent form after the surgery date.
- You failed to provide 5 out of the 10 patients enrolled in the study with an IRB approved informed consent form.
- You signed two of the informed consent forms approximately one month after the patients signed them.

For your information, informed consent must be obtained by the subject or the subject's legally authorized representative prior to his or her participation in an investigational study. This includes obtaining the subject's or the legally authorized representative's signature indicating that the study subject has been informed of the risks and benefits of participating in the clinical trial.

Failure to maintain IRB approval of study (21 CFR 812.100 & 812.150(a)(6)).

You failed to maintain IRB approval of the study from February 2001 through August 2001. [REDACTED] submitted a final report to the IRB on February 13, 2001 closing the study. This closure took place before patients completed their 24-month follow-up visits. As a clinical investigator, you must ensure that the investigation is conducted according to applicable FDA regulations, including the submission of final reports.

Failure to maintain accurate, complete, and current device accountability records (21 CFR 812.100 and 21 CFR 812.140(a)(2)).

A review of the [REDACTED] documentation supplied by you during the inspection did not accurately reflect the use or disposition of devices received from the sponsor. A letter from the sponsor, dated July 26, 2002, states that "all" of the [REDACTED] shipped to your institution were returned. However, documentation at your site shows that 14 [REDACTED] were delivered to you and you implanted 3 of these devices; there is no documentation to show the disposition of the remaining 11 devices. If three were implanted then all devices could not have been returned to the sponsor. FDA regulations require that an investigator maintain accurate, complete, and current records

related to the receipt and use or disposition of all investigational devices. **Please explain the disposition of the remaining devices.**

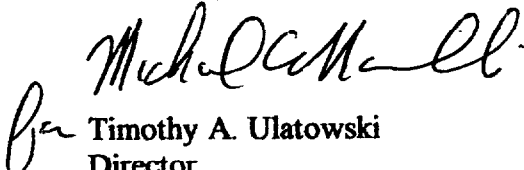
The deviations listed above are not intended to be an all-inclusive list of deficiencies that may exist in connection with this clinical study. It is your responsibility as a clinical investigator to ensure that an investigation is conducted according to the signed agreement, the investigational plan,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

Within fifteen (15) working days of your receipt of this letter, please inform FDA of the corrective actions taken to remedy the deviations noted above. Failure to respond could result in regulatory action without further notice. Please send all information requested 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), 2094 Gaither Road, Rockville, Maryland 20850, Attention: Pamela M. Reynolds.

A copy of this Warning 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 the Florida District Office.

Please direct all questions concerning this matter to Ms. Pamela Reynolds at (301) 594-4723, ext. 155.

Sincerely yours,


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

cc:

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