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Warning Letter

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

Via Federal Express

James A. Hill, M.D.
11308 North Pennsylvania Avenue
Oklahoma City, Oklahoma 73120

Dear Dr. Hill:

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. Ms. Margaret M. Annes of FDA Dallas District Office conducted the inspection at your site on June 6-19, 2002.

The purpose of the inspection was to determine if your activities as a clinical investigator in the [REDACTED] complied with applicable FDA regulations. The [REDACTED] in the study are devices as that term is defined in Section 201(h) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 321(h)].

The inspection was conducted under an FDA compliance program designed to ensure that data and information contained in requests for Investigational Device Exemptions (IDE), Premarket Approval Applications (PMA), and Premarket Notifications (510(k)) 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. The [REDACTED] supports PMA [REDACTED] and [REDACTED].

Our review of the inspection report prepared by the Dallas District Office reveals violations of requirements of Title 21, Code of Federal Regulations (CFR), Part 50 – Protection of Human Subjects and Part 56 – Institutional Review Boards. At the conclusion of the inspection, Ms. Annes listed her findings on a Form FDA-483 “Inspectional Observations,” and discussed these findings with you.

We acknowledge receipt of a copy of your July 5, 2002, response to Ms. Annes’ findings. Your response does not adequately address all of the FDA-483 items, nor does it contain supporting documentation of any corrections.

This letter informs you of the violations found during this inspection and our subsequent review of the inspection report. The following violations were observed:

1. Failure to ensure that the requirements for obtaining and documenting informed consent were met [21 CFR 50.20 and 50.27]

You did not obtain informed consent from all subjects participating in the clinical study. There is no documentation to determine when all subjects consented. Not all consent forms were signed and dated by the subjects in the study. For example, someone other than subjects [REDACTED] and [REDACTED] entered the date next to the subject's signature. In addition, there is no consent for subject [REDACTED].

2. Failure to conduct the study in accordance with the conditions of approval by the reviewing Institutional Review Board [21 CFR 56.103]

You did not comply with the conditions of IRB approval, including your signed investigator's agreement and study protocol. You did not follow the IRB-approved study procedures. You did not ensure the accuracy, completeness, and timeliness of information recorded and reported. Many subject case histories lack pertinent information. Your records contained unexplained discrepancies, including the enrollment of a [REDACTED] into the study.

You could not fully account for the receipt, use, and disposition of all devices at the clinical site. Your records do not contain a complete registry of subjects implanted at the site. At least one of your subjects documented in your records did not receive the device.

According to your records, [REDACTED] initially approved the clinical study on July 17, 1997. There is no documentation that another IRB had reviewed and approved the study before this date and before you enrolled [REDACTED] subjects.

The above violations are not intended to be an all-inclusive list of deficiencies that may exist in the clinical study. We recommend that you review your records for other deficiencies and correct them accordingly.

Please acknowledge receipt of this letter within 15 working days. Your response must include (1) each step that has been or will be taken to completely correct the current violations and to prevent the recurrence of similar violations; (2) the time within which correction will be completed; (3) any reason why the corrective action has not been completed with the response time; and (4) any documentation necessary to show that the correction has been achieved.

In addition, please provide a list of your current investigational studies and include the name of the study sponsor and the date of IRB approval. Failure to achieve prompt correction may result in enforcement action without further notice.

Direct your response to the Food and Drug Administration, Center for Devices and Radiological Health, Office of Compliance, Division of Bioresearch Monitoring,

Program Enforcement Branch I (HFZ-311), 2098 Gaither Road, Rockville, Maryland 20850, Attention: Kevin M. Hopson, Consumer Safety Officer. If you have any questions or require additional time to respond, please call Mr. Hopson at (301) 594-4720, extension 128.

A copy of this letter has been sent to FDA's Dallas District Office, 4040 North Central Expressway, Suite 300, Dallas, Texas 75204. We request that you send a copy of your response to that office.

Sincerely yours,

Charma Kounor, RPh, RAC

for

Philip J. Frappaolo
Acting Director
Office of Compliance
Center for Devices and
Radiological Health

cc: [REDACTED]
[REDACTED]
[REDACTED]
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