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APR 11 2005

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

Via Federal Express

WARNING LETTER

Gerald L. Grubbs, M.D.
842 Sunset Lakes Boulevard, Suite 301
Venice, Florida 34292

Dear Dr. Grubbs:

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. Mr. Keith Schwartz, an investigator from the FDA's Florida District Office conducted the inspection from December 29, 2004 through January 21, 2005. The purpose of the inspection was to determine if your activities and procedures as a clinical investigator for the [REDACTED] study sponsored by [REDACTED] complied with applicable FDA regulations. The [REDACTED] 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).

The FDA conducted the inspection 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. The program also ensures that human subjects are protected from undue hazard or risk during 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 close of the inspection, Mr. Schwartz presented a Form FDA 483 “Inspectional Observations” to you for review and discussed the listed deviations. The deviations noted on the Form FDA 483 and our subsequent inspection report review are discussed below:

Failure to conduct the study in accordance with the investigational plan, the investigator agreement, and FDA regulations (21 CFR 812.100, 21 CFR 812.110(b) and 21 CFR 812.140(a)(3) and (e)).

As a clinical investigator you are required to ensure that investigations are conducted according to the signed agreement, the investigational plan, and applicable FDA regulations, as well as any conditions of approval imposed by the IRB or FDA. You are also responsible for maintaining accurate, complete, and current records relating to your participation in this investigation. You failed to satisfy these requirements in that you transferred custody of the study records to the [REDACTED] for storage without obtaining the sponsor's approval. Furthermore, these records could not be produced at the time of the inspection and had apparently been discarded. During the closeout discussion with Mr. Schwartz you stated that you were not responsible for the study records because it was over two years since you had been notified of the studies initial termination in September 2000 and that you were unaware of a July 2002 letter from the sponsor addressed to you stating that the study was being re-opened and asking you to maintain study related records. Although the sponsor terminated the study in September 2000 and the required period of 2 years for retaining the documents after study termination had passed, you are still responsible for adhering to the protocol requirements which state that **"Records concerning the clinical study cannot be disposed or custody of the records cannot be transferred without prior approval from the Sponsor."** In addition, you failed to notify FDA within 10 working days after withdrawing from the responsibility to maintain the records and transferring custody, as required by FDA regulation. The missing records included the following:

- original Case Report Forms (CRFs);
- informed consent forms;
- source documentation concerning percent residual stenosis in the form of subject notes made from radiographs for subjects [REDACTED] and [REDACTED];
- source documentation pertaining to color Doppler ultrasounds for the following subjects' follow-up visits: [REDACTED] (1 & 6 months); [REDACTED] (1, 6 & 12 months); [REDACTED] (1 & 6 months); [REDACTED] (12 months); [REDACTED] (6 months); [REDACTED] (1 month); [REDACTED] (1 & 6 months); [REDACTED] (1, 6 & 12 months); [REDACTED] (1 month); [REDACTED] (6 months); [REDACTED] (1 & 6 months); and [REDACTED] (1, 6, & 12 months).

Failure to provide the sponsor with sufficient accurate financial information (21 CFR 812.100) and (21 CFR 54.4(b)).

The inspection revealed that there was no clinical investigator financial disclosure information available for review during the inspection. The regulations state that a clinical

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investigator shall disclose to the sponsor sufficient accurate financial information to allow the applicant to submit complete and accurate certification or disclosure statements.

The above described deviations are not intended to be an all-inclusive list of deficiencies that may exist in this clinical study. It is your responsibility as a clinical investigator to ensure that you adhere to applicable FDA regulations.

Within fifteen (15) working days after receiving this letter please provide written documentation of the additional specific steps you have taken or will take to correct these violations and prevent the recurrence of similar violations in current and future studies. Failure to respond to this letter and take appropriate corrective action could result in FDA taking regulatory action without further notice to you. Please send your response to:

Food and Drug Administration, Center for Devices and Radiological Health, Office of Compliance, Division of Bioresearch Monitoring, Program Enforcement Branch (HFZ-312), 2094 Gaither Road, Rockville, Maryland 20850, Attention: Viola Sellman, Chief, Program Enforcement Branch.

We are also sending a copy of this letter to FDA's Florida District Office, 555 Winderley Place, #200, Maitland, Florida 32751. We request that you also send a copy of your response to that office. If you have any questions, please contact Ms. Sellman at (240) 276-0125, or by email at vxs@cdrh.fda.gov.

Sincerely yours,



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