



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville, Maryland 20850

WARNING LETTER

VIA FEDERAL EXPRESS

DEC 5 2007

Susan J. Wheatley, M.D.
1250 Upper Hembree Road
Suite E
Roswell, Georgia 30076

Dear Dr. Wheatley:

This Warning Letter is to inform you of objectionable conditions observed during the Food and Drug Administration (FDA) inspection conducted at your clinical site from April 12 to May 10, 2007 by an investigator from the FDA Atlanta District Office. The purpose of this inspection was to determine whether activities and procedures related to your participation in the clinical study of the ^{(b) (4)}

^{(b) (4)}

^{(b) (4)} complied with applicable federal regulations. The

^{(b) (4)} 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). This letter also requests prompt corrective action to address the violations cited and discusses your written response, dated June 7, 2007, to the noted violations.

The inspection was conducted under a program designed to ensure that data and information contained in requests for Investigational Device Exemptions (IDE), Premarket Approval (PMA) applications, and Premarket Notification submissions (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.

Our review of the inspection report prepared by the district office revealed serious violations of Title 21, Code of Federal Regulations (21 C.F.R.) Part 812 -- Investigational Device Exemptions and Part 50 -- Protection of Human Subject. At the close of the inspection, the FDA investigator presented an inspectional observations form FDA 483 for your review and discussed the observations listed on the form with you and Ms. Sue Winans, Research Coordinator. The deviations noted on the FDA 483, your written response, and our subsequent review of the inspection report are discussed below:

Failure to adhere to informed consent requirements and failure to follow the investigator's agreement, investigational plan, and applicable FDA regulations [21 C.F.R. 50.20 and 21 C.F.R. 812.100].

As a clinical investigator you are responsible for ensuring that informed consent is obtained using an Institutional Review Board (IRB) approved consent document prior to any study related procedures [21 C.F.R. 50.20]. You are also responsible for ensuring that an

investigation is conducted according to the signed agreement, the investigational plan, and applicable FDA regulations [21 C.F.R. 812.100]. You failed to adhere to the above stated regulations. Examples of this failure include but are not limited to the following:

Written informed consent was not obtained from the following 17 subjects prior to initiating study related procedures (b) (4)

(b) (4)

Subjects (b) (6)

(b) (6)

In your response, you acknowledge these failures to obtain informed consent and state that all of these occurrences were documented as protocol deviations. You also state that, in the future, a subject's informed consent to participate in a study will be obtained prior to the initiation of any study related (b) (4) including (b) (4). Your response is inadequate, in that it does not indicate specific steps that you have taken or plan to take to ensure that proper consent of subjects is obtained. Please provide us with details of the specific training and/or procedures that you have or will put in place to ensure that all subjects are properly consented prior to any study related (b) (4) when conducting future studies.

Failure to ensure that an investigation is conducted according to the signed agreement, investigational plan, and applicable FDA regulations and failure to maintain accurate, complete, and current records relating to the investigator's participation in an investigation [21 C.F.R. 812.100, 21 C.F.R. 812.110(b), and 21 C.F.R. 812.140(a)].

As a clinical investigator, you have the responsibility to conduct the clinical investigation in accordance with the signed agreement, investigational plan, and applicable FDA regulations [21 C.F.R. 812.100 and 812.110(b)]. In addition, you have the responsibility to maintain accurate, complete, and current records relating to the investigator's participation in an investigation, including records of each subject's case history and records showing the dates of and reasons for each deviation from the protocol [21 C.F.R. 812.140(a)]. You failed to adhere to the above stated regulations. Examples of these failures include but are not limited to the following:

- The (b) (4) section of the protocol (p. 9) states that (b) (4). A review of subject files revealed that pre-(b) (4) were not performed on 17 of the 20 subjects, nor was there any documentation of these deviations. [21 C.F.R. 812.100 and 812.140(a)(4)]

In your response, you state that it is not your standard of care to perform (b) (4) before an (b) (4)

(b) (4) You also state that, in the future, clarification regarding inclusion criteria and standard of care noted in the protocol or instructions for use will be obtained prior to enrollment of the first subject of a study. Your response is inadequate in that it does not provide specific steps you have taken or intend to take to prevent these deviations from occurring and to ensure that, if they do occur, they will be documented as deviations in your

records. Please submit a corrective and preventative action plan to assure adherence to study protocols and maintenance of accurate, complete, and current records when conducting future studies of FDA regulated devices.

- The (b) (4) section of the protocol (pp. 9-10) requires that a (b) (4) be performed (b) (4) were not performed for the following subjects: (b) (6) [21 C.F.R. 812.100]

In your response, you acknowledge that the above stated subjects did not have the (b) (4) and/or (b) (4). You assert that all patients would have received a (b) (4) had there been any question of patient well-being. You state that, in the future, you will obtain clarification from the sponsor prior to screening any potential subjects regarding protocol criteria and standard of care. Additionally, you state that you will ensure that the study budget allows for all study related procedures not covered by insurance. Your response is inadequate in that it does not include specific steps you intend to take to ensure adherence to study protocols when conducting FDA regulated studies. Please submit the corrective and preventative action plan to assure adherence to the study protocols when conducting FDA regulated studies.

- Records of each subject's case history are not all accurate, complete, and current. Specifically, (b) (4) that identify the post-(b) (4) for the day of the procedure were missing and the post-(b) (4) could not be verified for Subjects (b) (6) [21 C.F.R. 812.140(a)(3)]

In your response, you state that the (b) (4) for subjects (b) (6) appeared to have been misplaced after the procedure. You also state that, in the future, you will ensure (b) (4) are stapled securely to the CRF. Your response is inadequate in that it does not indicate specific measures that you have taken or intend to take to ensure that all records pertaining to each subject's case history are accurate, complete, and current. Please submit a detailed corrective and preventative action plan.

The violations described above are not intended to be an all inclusive list of problems that may exist with your clinical study. It is your responsibility as a clinical investigator to ensure compliance with the Act and applicable regulations.

Within fifteen (15) working days of receiving this letter, please provide written documentation of the actions you have taken or will take to correct these violations and prevent the recurrence of similar violations in current or future studies for which you are the clinical investigator. In addition, please provide a complete list of all clinical trials in which you have participated for the last five years, including the name of the study and test article, the name of the sponsor, the number of subjects enrolled, and the current status of the study. Failure to respond to this letter and take appropriate corrective action could result in the FDA taking regulatory action without further notice to you. In addition, FDA could initiate disqualification proceedings against you in accordance with 21 C.F.R. 812.119.

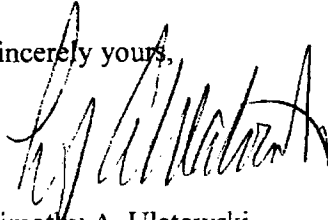
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You will find information to assist you in understanding your responsibilities and planning your corrective actions in the FDA Information Sheets Guidance for Institutional Review Boards and Clinical Investigators, which can be found at <http://www.fda.gov/oc/ohrt/irbs/>. Any submitted corrective action plan must include projected completion dates for each action to be accomplished. Send your response to: Attention: Linda Godfrey, Food and Drug Administration, Center for Devices and Radiological Health, Office of Compliance, Division of Bioresearch Monitoring, 9200 Corporate Boulevard, HFZ-310, Rockville, Maryland 20850.

A copy of this letter has been sent to Atlanta District Office, 60 Eighth Street, NE, Atlanta, Georgia 30309. Please send a copy of your response to that office.

If you have any questions, please contact Linda Godfrey at 240-276-0125 or via e-mail at Linda.Godfrey@fda.hhs.gov.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Timothy A. Ulatowski". The signature is written in a cursive style with a large, stylized initial "T".

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