DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville, Maryland 20850

JUL 31 2007

NOTICE OF INITIATION OF DISQUALIFICATION PROCEEDING AND OPPORTUNITY TO EXPLAIN (NIDPOE)

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Paul A. Overlie, M.D.
Texas Cardiac Center
3710 21st Street
Lubbock, TX 79410

Dear Dr. Overlie:

Between October 17 and 20, 2006, a Food and Drug Administration (FDA) investigator conducted an inspection of the following clinical studies in which you participated: the [redacted] The inspection was conducted as part of the FDA's Bioresearch Monitoring Program which includes inspections designed to monitor the conduct of research involving investigational products.

Based on our evaluation of information obtained by the Agency, we believe that you have repeatedly and deliberately violated regulations governing the proper conduct of clinical studies involving investigational products as published under Title 21, Code of Federal Regulations (CFR), Part 812 – Investigational Device Exemptions.

This letter provides you with written notice of the matters under complaint and initiates an administrative proceeding, described below, to determine whether you should be disqualified from receiving investigational products as set forth under 21 CFR 812.119.

A listing of the violations follows. The applicable provisions of 21 CFR 812 are cited for each violation.

Failure to ensure that an investigation is conducted according to the signed agreement, the investigational plan and applicable FDA regulations, for protecting the rights, safety, and welfare of subjects under the investigator's care [21 CFR 812.100].

Under 21 CFR 50.20 and 812.100, 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. You failed to adhere to these regulations because you did not receive informed consent from the subject [redacted]. Although the subject expired on 1[redacted]/03, the informed consent form (ICF) was signed on 3/20/03.

Failure to maintain accurate, complete, and current case histories [21 CFR 812.140(a)(3)].

Pursuant to 21 CFR 812.140(a)(3), a clinical investigator is responsible for maintaining accurate and complete records of each subject's case history. Examples of your failure to adhere to the above stated regulation include but are not limited to the following:

a. The records for subject [redacted] are not accurate or complete. The following documentation maintained in the subject's medical file is in question due to the fact that the subject expired on 1[redacted]/03, before any of these events occurred:

i. There are records of telephone conversations between this subject and the study coordinator Ms. Zamora on 2/4/03, 3/18/03, 5/23/03, 5/28/03, and 6/3/05.

ii. There is a record of a telephone conversation between Ms. Zamora and the subject's cardiologist's office on 3/14/03, documenting that the subject was seen in the office on 3/10/03, and had a stress test on 3/12/03.

b. During the inspection, you told the FDA investigator that the signature on the following records is not yours:

i. The protocol deviation form dated 8/25/03

ii. The [redacted] follow-up Serious Adverse Events (SAE) form dated 6/24/04

iii. The 3-year follow-up form dated 6/3/05

c. The records for subject [redacted] are not accurate or complete in that although the subject expired on 3[redacted]/04, Case Report Forms (CRF) document [redacted] and [redacted] follow-up assessments made via telephone by your study coordinator on 8/27/04 and 2/18/05. The dates of these events are not possible in that the subject expired before the date these assessments were made.

d. There is an [redacted] follow-up CRF for subject [redacted] on 3/23/04. However, there is no record of a visit by the subject on that day in the patient procedure history.

e. The date of the [redacted] follow-up visit on the CRF for subject [redacted] is 5/21/04. However, the clinical investigator signed the CRF approximately four months later, on 9/16/04.

Submission of false information to the sponsor [21 CFR 812.119].

Under 21 CFR 812.119, submission of false information to the sponsor or in any required report is grounds for the initiation of disqualification proceedings. The case report forms for subject [redacted] document 2- and 3-year follow-up visits and an electrocardiogram (ECG) contained false information, as the subject expired on 1/[redacted]/03.

According to your response of 10/20/06, discrepancies were not discovered until 2005. The current FDA inspection revealed that the first example of your failure to personally supervise the FDA-regulated clinical trials you were involved in was in 2002. Although your response to the Form FDA 483 includes plans for overseeing and implementing corrective actions, it does not indicate that you, personally, will be responsible for any of these corrective actions. Please respond with specific corrective and preventive actions you have taken or plan to take to prevent these violations from occurring in future clinical studies of FDA-regulated devices. Please include time frames for all your corrective and preventive actions as well as your written plans for monitoring your corrective and preventive actions to ensure that they are effective.

This letter is not intended to be an all-inclusive list of deficiencies with your clinical studies of investigational medical devices. It is your responsibility to ensure adherence to each requirement of the law and relevant regulations.

On the basis of the above listed violations, FDA asserts that you have repeatedly and deliberately failed to comply with the cited regulations and it proposes that you be disqualified as a clinical investigator. You may reply to the above stated issues, including an explanation of why you should remain eligible to receive investigational products and not be disqualified as a clinical investigator, in a written response or at an informal conference in my office. This procedure is provided for by 21 CFR 812.119.

Within fifteen (15) days of receipt of this letter, write or call Michael Marcarelli, PharmD at (240) 276-0125 to arrange a conference time or to indicate your intent to respond in writing. Your written response must be forwarded within thirty (30) days of receipt of this letter. Your reply should be sent to:

Food and Drug Administration
Center for Devices and Radiological Health
Office of Compliance

Division of Bioresearch Monitoring (HFZ-310)
9200 Corporate Boulevard
Rockville, Maryland 20850
Attention: Michael Marcarelli, PharmD

Should you request an informal conference, we ask that you provide us with a full and complete explanation of the above listed violations. You should bring with you all pertinent documents, and you may be accompanied by a representative of your choosing. Although the conference is informal, a transcript of the conference will be prepared. If you choose to proceed in this manner, we plan to hold such a conference within 30 days of your request.

At any time during this administration process, you may enter into a consent agreement with FDA regarding your future use of investigational products. Such an agreement would terminate this disqualification proceeding. Enclosed you will find a proposed agreement between you and FDA.

The Center will carefully consider any oral or written response. If your explanation is accepted by the Center, the disqualification process will be terminated. If your written or oral responses to our allegations are unsatisfactory, or we cannot come to terms on a consent agreement, or you do not respond to this notice, you will be offered a regulatory hearing before FDA, pursuant to 21 CFR Part 16 (enclosed) and 21 CFR 812.119. Before such a hearing, FDA will provide you notice of the matters to be considered, including a comprehensive statement of the basis for the decision or action taken or proposed, and a general summary of the information that will be presented by FDA in support of the decision or action. A presiding officer free from bias or prejudice and who has not participated in this matter will conduct the hearing. Such a hearing will determine whether or not you will remain entitled to receive investigational products. You should be aware that neither entry into a consent agreement nor pursuit of a hearing precludes the possibility of a corollary judicial proceeding or administrative remedy concerning these violations.

Sincerely yours,

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

Enclosure: Consent Agreement
21 CFR Part 16