

By Facsimile Transmission and Overnight Delivery

Wayne E. Spencer, M.D.

April 20, 2011

(b)(6)

**NOTICE OF INITIATION OF DISQUALIFICATION PROCEEDINGS AND
OPPORTUNITY TO EXPLAIN**

Dear Dr. Spencer:

Between November 16, 2010 and November 18, 2010, Food and Drug Administration (FDA) (hereafter referred to as the "agency") investigators conducted an inspection of the following clinical study in which you participated as a clinical investigator: *A 28-Day Study Evaluating the Safety of* (b)(4)

(b)(4)

(b)(4) This inspection was conducted as part of the FDA's Bioresearch Monitoring Program, which includes inspections designed to review the conduct of research involving investigational products governed under Title 21, Code of Federal Regulations (CFR) Part 312 (available at <http://www.access.gpo.gov/cgi-bin/cfrassemble.cgi?title=201021>).

At the end of the inspection, a Form FDA 483, Inspectional Observations, was issued to and discussed with you. Based on our evaluation of information obtained by the investigators, we believe that you have repeatedly or deliberately violated regulations governing the proper conduct of clinical studies (21 CFR Part 312) and repeatedly or deliberately submitted false information in a required report to the sponsor involving an investigational new drug.

This letter provides you with written notice of the matters complained of and initiates an administrative proceeding, described below, to determine whether you should be disqualified from receiving investigational articles as set forth under 21 CFR § 312.70.

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

1. You failed to fulfill the general responsibilities of an investigator. [21 CFR § 312.60].

As a clinical investigator, your general responsibilities under 21 CFR § 312.60 include ensuring that an investigation is conducted according to the signed investigator statement, the investigational plan, and applicable regulations; for protecting the rights, safety, and welfare of subjects under your care; and for the

control of drugs under investigation. You signed a Form FDA 1572, Statement of Investigator, on November 4, 2009 and on multiple occasions thereafter, you specifically agreed to personally conduct the clinical studies or to supervise those aspects of the studies that you did not personally conduct. While you may delegate certain study tasks to individuals qualified to perform them, such delegation requires adequate supervision of those to whom you delegate authority. You are responsible for the oversight of study personnel and for reviewing the work of study personnel to ensure that they follow the investigational plan and procedures.

Our investigation revealed that you failed to fulfill your responsibilities as a clinical investigator in that you failed to adequately oversee study activities and failed to supervise study personnel. Your lack of adequate supervision resulted in your failure to ensure that the study was conducted according to the signed investigator statement, the investigational plan, and the applicable regulations. For example:

- A. Two members of your staff enrolled in the study under false names and false dates of birth as Subjects (b)(6) and (b)(6). You signed the subjects' enrollment log on 2/25/2010 and the subjects consent forms on 1/8/2010 despite your knowledge of the falsification. You admitted the falsifications to the FDA investigators in your sworn affidavit.
- B. Section 7.3.1 of the protocol requires subjects to be 50 years of age and older. Nevertheless, you enrolled your staff as Subjects (b)(6) and (b)(6) using deliberately fabricated names and birth dates to make it appear that they met the eligibility criteria of the protocol.
- C. Of the seven subjects you enrolled in the study, two were directly involved in the study as "Study Coordinator" and "Regulatory Personnel" in violation of the specific exclusion criterion set forth in Section 7.3.2 of the protocol. The internal investigation revealed and you admitted to the FDA investigators that the two employees had enrolled in the study under assumed names and false dates of birth.

Subject #	(b)(6)	(b)(6)
Screening #	(b)(6)	(b)(6)
Falsified DOB	(b)(6)	(b)(6)
Assumed Name	(b)(6)	(b)(6)
Date Screened	1/8/10	1/8/10
Date Enrolled	1/11/10	1/11/10
Randomization #	0031-002672	0031-002676
Date Completed	2/19/10	2/19/10

2. **You failed to prepare and maintain adequate and accurate case histories that record all observations and other data pertinent to the investigation on each individual administered the investigational drug, including case report forms and supporting data. [21 CFR § 312.62(b)].**

An investigator is required to prepare and maintain adequate and accurate case histories that record all observations and other data pertinent to the investigation on each individual administered the investigational drug or employed as a control in the investigation. As defined by 21 CFR § 312.62(b), case histories include case report forms and supporting data, including, for example, subject medical records and signed and dated informed consent forms.

As noted in items 1.A. through 1.C., two members of your staff enrolled in the study under false names and false dates of birth as Subjects (b)(6) and (b)(6). You signed the subjects' enrollment log on 2/25/2010 and the subjects consent forms on 1/8/2010 despite your knowledge of the falsification.

3. **You repeatedly and deliberately submitted false information to the sponsor in a required report. [21 CFR § 312.70(a)].**

You submitted the following false information to the sponsor:

- A. You submitted Subjects' (b)(6) and (b)(6) randomization confirmations (forms that are submitted to the sponsor to confirm a subject's enrollment in the study, which contain information about the subject) to the sponsor via facsimile transmission on 1/8/2010 even though you were aware that the subjects were enrolled using false dates of birth and assumed names.
- B. The protocol requires physical exam of the study participants prior to enrollment. Nevertheless, you completed and signed the physical exam forms for Subjects (b)(6) and (b)(6) on 1/8/10 without actually performing the physical examinations and submitted the physical exam forms to the sponsor. You stated to the FDA investigators that you did not perform the physical exams because "you felt confident that the subjects had previous exams and were healthy."
- C. You signed Subject (b)(6) source document on 2/17/2010 indicating that you reviewed and verified that all pertinent information was entered on the application sections of the case report forms and submitted the source document to the sponsor.

This letter is not intended to be an all-inclusive list of deficiencies with your clinical studies of investigational vaccines. 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 or deliberately failed to comply with the cited regulations and repeatedly or deliberately submitted false information to the sponsor. Accordingly, FDA proposes that you be disqualified as a clinical investigator. You may reply to the above stated findings, including any explanation of why you should remain eligible to receive investigational articles 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 regulation 21 CFR § 312.70.

Within fifteen (15) business days of receipt of this letter, write me to arrange a conference time or to indicate your intent to respond in writing. Your written response must be forwarded within thirty (30) business days of receipt of this letter. If you do not respond within fifteen (15) business days, the right to file a response will be waived.

Your reply should be sent to:

Mary A. Malarkey, Director
Office of Compliance and Biologics Quality
Center for Biologics Evaluation and Research
1401 Rockville Pike, Suite 200N
Rockville, Maryland 20852-1488

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. A representative of your choosing may accompany you. 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.

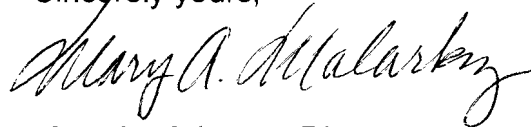
At any time during this administrative process, you may enter into a consent agreement with FDA regarding your future use of investigational articles. Such an agreement would terminate this disqualification proceeding. Enclosed you will find a proposed agreement between you and FDA.

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 (available at the internet address identified on page 1 of this letter) and 21 CFR § 312.70. 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 who has not participated in this matter will conduct the hearing. The Commissioner will determine whether or not you will remain entitled to receive investigational articles. You should be aware that neither entry into a

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consent agreement nor pursuit of a hearing precludes the possibility of a corollary judicial proceeding or administrative remedy concerning these violations.

Sincerely yours,

A handwritten signature in black ink, reading "Mary A. Malarkey". The signature is written in a cursive style with a large, looping initial "M".

Mary A. Malarkey, Director
Office of Compliance and Biologics Quality
Center for Biologics Evaluation and Research

Enclosure: Proposed consent agreement