DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

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

HAND DELIVERED
BY FDA-FL-DO

JAN 2 0 2006

Mr. Christopher M. Phillips
11196 Lakeland Circle
Ft. Myers, FL 33193-6907

Dear Mr. Phillips:

Between March 10, 2003 and April 3, 2003, Ms. Eileen J. Bannerman, representing the Food and Drug Administration (FDA), conducted an investigation and met with Dr.[ ] your subinvestigator, to review your conduct of the following clinical studies in which you participated as the clinical investigator:

Protocol[ ]entitled: "A 12 Week, Double-Blind, Placebo-Controlled, Parallel Group Study to Assess the Efficacy, Safety and Tolerability of[ ]in Subjects with Restless Legs Syndrome (RLS) Suffering from Periodic Leg Movements of Sleep (PLMS)," performed for[ ]

Protocol[ ]entitled: "Comparison of Efficacy and Safety of Zolpidem-MR 12.5 mg and Placebo in Patients with Primary Insomnia. A Double-Blind, Randomized, Placebo-Controlled, Parallel-Group Study," performed for Sanofi-Synthelabo Research; and

Protocol[ ]entitled: "A Phase III, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group, Multicenter Study to Assess the Efficacy and Safety of a Modified Release Formulation of[ ]in Elderly Primary Insomnia Patients with Sleep Maintenance Difficulties," performed for[ ]

We learned prior to the start of the inspection that you had left United Sleep Medicine where the studies were conducted. We note that Dr.[ ]kept custody of the study records.

This inspection is a part of the FDA's Bioresearch Monitoring Program, which includes inspections designed to evaluate the conduct of research and to ensure that the rights, safety and welfare of the human subjects of those studies have been protected.

At the conclusion of the inspection, Ms. Bannerman presented and discussed with subinvestigator Dr.[ ]the items listed on the Form FDA 483, Inspectional Observations. We acknowledge Dr.[ ]response dated May 1, 2003.

Based on our evaluation of the information obtained, the Center for Drug Evaluation and Research (Center) believes that you have repeatedly or deliberately violated regulations governing the proper conduct of clinical studies involving investigational products as published under Title 21, Code of Federal Regulations (CFR), Part 312 (copy enclosed) and that you submitted false information in a required report to FDA or the sponsor.

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 312.70.

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

1. **You submitted false information to FDA or the sponsor in a required report [21 CFR 312.70(a)].**

   a. You submitted documents containing falsified signatures for[ ]M.D., Ph.D., to the sponsors of Protocols[ ]and[ ]

   Dr.[ ]indicated in an affidavit that he was on extended leave from July 2002 through November 18, 2002. According to this affidavit, Dr.[ ]does not believe that the signatures on the following documents, signed during the time he was on leave, are his:

   1) Investigator Protocol Agreement page for Protocol[ ]dated 9/25/02
   2) Clinical Trial Protocol Amendment signature page for Protocol[ ] Amendment No. 2 dated 11/13/02
   3) Clinical Trial Protocol Amendment signature page for Protocol[ ] Amendment No. 3 dated 11/13/02
   4) Form FDA 1572 for Protocol[ ]dated 10/11/02
   5) Form FDA 1572 for Protocol[ ]dated 11/14/02

   Dr.[ ]also indicated in the affidavit that he does not believe the signatures on the following study documents are his:

   6) Two Site Staff Signature Sheets for Protocol [ ]dated 2/1/02
   7) Controlled Substance Authorization Form for Protocol[ ]dated 5/23/02
   8) Form FDA 1572 for Protocol[ ]dated 2/25/03
   9) Screening Visit Physical Exam Form (Protocol[ ] for subject[ ]/03965 dated 5/8/02

10) Screening Visit Physical Exam Form (Protocol [ ] for subject [ ] 03967 dated 5/10/02

11) Screening Visit Physical Exam Form (Protocol [ ] for subject [ ] 03969 dated 5/15/02

b. You submitted false information to FDA or the sponsor concerning your medical qualifications and credentials.

1) For protocol [ ] you submitted false information to FDA and the sponsor indicating that you possess a Family Nurse Practitioner (FNP) degree when you had not undergone such training.

On Form FDA 1572 for this protocol you indicated that you were a FNP. You signed and dated that form on September 17, 2002.

On your CV attached to the Form FDA 1572, you claimed to have obtained a Masters of Science in Nurse Practitioner degree from Ashford University (2000-2002) in London, England. We note that the Federal Trade Commission has obtained a permanent injunction that, among other things, prevents the entities that operated the website www.ashforduniversity.net (Mountain View Systems, Ltd., et al,) from selling any academic degree or academic verification material in or from the United States or to any U.S. citizen or resident and from misrepresenting or assisting others in misrepresenting (1) that the holder of any academic degree has completed and shown proficiency in a curriculum recognized as necessary to earn the academic degree or (2) that any academic degree has been issued by a college, university, or other educational institution[1]. Currently, the website http://www.ashforduniversity.net is not active. Based on this injunction, it appears that your degree from Ashford University is not valid.

Furthermore, we understand that, in a letter dated July 10, 2002, the North Carolina Board of Nursing specifically instructed you to cease and desist from practicing as a nurse practitioner applicant or using the title, until such time as you received notification of eligibility to sit for a national certification exam. You signed and dated Form FDA 1572 for Protocol [ ] on September 17, 2002, after the date of this letter.

2) For protocols [ ] you submitted false information to FDA and the sponsor indicating that you had a Ph.D., degree.

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1 *See* Stipulated Final Order for Permanent Injunction and Settlement of Claims, Federal Trade Comm'n v. Mountain View Sys., Ltd., (D.D.C. signed Dec. 1, 2003) (No. 03-CV-00021-RMC).

On Forms FDA 1572 for these protocols you indicated that you possessed a Ph.D., degree. You signed and dated these forms on September 17, 2002 (for protocol[ ] January 7, 2002 (for protocol[ ] and March 19, 2002 (for protocol[ ]

Your claim to possess such a degree appears to be based on a Ph.D., in Nursing Administration you purportedly obtained from Brentwick University (2001-2002) in London, England. We note that the Federal Trade Commission has obtained a permanent injunction that, among other things, prevents the entity that operated the website www.brentwickuniversity.org (Mountain View Systems, Ltd., et al,) from selling any academic degree or academic verification material in or from the United States or to any U.S. citizen or resident and misrepresenting or assisting others in misrepresenting (1) that the holder of any academic degree obtained from Mountain View Systems Ltd., et al., has completed and shown proficiency in a curriculum recognized as necessary to earn the academic degree or (2) that any academic degree has been issued by a college, university, or other educational institution[2]. Currently, the website http://www.brentwickuniversity.org is not active. Based on this injunction, it appears that your degree from Brentwick University is not valid.

2. You failed to conduct the study in accordance with the protocol [21 CFR 312.60].

a. For Protocol[ ]the inclusion criteria required that during the screening nights (SN1 and SN2), the total sleep time (TST) be[ ]hours. Subjects[ ]/011 and[ ]/004 were enrolled despite SN2 TST of 442.5 minutes (7 hours 22.5 minutes) and 450 minutes (7 hours 30 minutes), respectively. The sponsor considered these major protocol violations for which no waivers were issued.

b. For Protocol[ ] the inclusion criteria required that subjects self-report wake times of > 60 minutes on at least 4 nights per week. However, the visit 1 source document for subject[ ]/25092 indicates that the subject self-reported wake times of > 60 minutes on only 2 nights in a 7-day period, and therefore did not meet the inclusion criteria.

c. Protocol[ ]required that orthostatic blood pressure measurements be recorded pre-dose and 2 hours post dose on the 2 consecutive nights prior to the Week 6 and 12 visits. However, for three subjects[ ]/03963 (on two different dates),[ ]/03962, and[ ]03967), the orthostatic measurements were not performed at the appropriate interval post dose.

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2 *See* Stipulated Final Order for Permanent Injunction and Settlement of Claims, Federal Trade Comm'n v. Mountain View Sys., Ltd., (D.D.C. signed Dec. 1, 2003) (No. 03-CV-00021-RMC).

3. You failed to prepare and maintain adequate and accurate records [21 CFR 312.62(b)].

a. Subject[ ]03968, enrolled in Protocol[ ] did not complete the Restless Legs Syndrome (RLS) Rating Scale questionnaire at the early withdrawal visit. However, the source document lists the RLS Rating Scale score at 22. There is no explanation as to how the score was determined.

b. In records for Protocol[ ]the following discrepancies between source documents and the case report forms (CRFs) were noted for the primary efficacy endpoint (mean wake time after sleep onset –WASO), without any explanation:

Subject	Visit	Information in Source Document	Information in CRF
[ ]/002	7/23/02	WASO: 97.0	WASO: 81.20
[ ]/002	7/22/02	WASO: 126.6	WASO: 79.15
[ ]/007	8/14/02	WASO: 86.0	WASO: 71
[ ]/007	8/15/02	WASO: 139.6	WASO: 119

c. In records for subject[ ]25092, enrolled in Protocol[ ]the following discrepancies between source documents and the CRFs were noted in the total sleep time (TST), a secondary efficacy endpoint, and total recording time (TRT), without any explanation:

Visit	Information in Source Document	Information in CRF
11/19/02	TST: 234 min.; Periodic Leg Movements with arousal: 2/hr	TST: 453 min.; Periodic Leg Movements with arousal: 3/hr
11/20/02	TRT: 481.2 min.	TRT: 472.0 min.
11/21/02	TRT: 480.1 min.	TRT: 458.0 min.

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

On the basis of the above listed violations, the Center asserts that you have submitted false information to FDA or the sponsor in a required report and that you repeatedly or deliberately failed to comply with the cited regulations. The Center proposes that you be disqualified as a clinical investigator. You may reply in writing or at an informal conference in my office 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. This procedure is provided for by regulation 21 CFR § 312.70.

Within fifteen (15) days of receipt of this letter, write or call me at (301) 594-0020 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:

Joanne L. Rhoads, M.D., MPH
Director,
Division of Scientific Investigations
Office of Medical Policy
Center for Drug Evaluation and Research
7520 Standish Place, Room #103
Rockville, Maryland 20855

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 all pertinent documents with you, and 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 the Center 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 the Center.

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 16 (enclosed) and 21 CFR 312.70. 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,

Joanne L Rhoads M.D.

Joanne L. Rhoads, M.D., MPH
Director
Division of Scientific Investigations
Office of Medical Policy
Center for Drug Evaluation and Research

Enclosures:
#1 - 21 CFR 312.70
#2 - 21 CFR 16
#3 - 21 CFR 50
#4 – Agreement