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 LETTER

JUN 27 2002

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Allyn M. Norman, D.O.
North Forest Medical Associates
2700 North Forest
Getzville, New York 14068

Dear Dr. Norman:

Between August 14 and 23, 2001, Mr. Donald Gordon, a Food and Drug Administration (FDA) investigator conducted an inspection of the following clinical study for which you served as the principal investigator: *A Randomized, Double Blind, Multicenter Study to Evaluate the Tolerability and Effectiveness of Rofecoxib (MK-0966) 25 q.d. Vs. Naproxen 500 mg b.i.d. in patients with Osteoarthritis, Study* [ ] performed for Merck & Co. This inspection was conducted as part of the FDA's Bioresearch Monitoring Program, which includes inspections designed to validate clinical studies on which drug approval may be based and to assure that the rights and welfare of the human subjects of these studies have been protected.

Based on our evaluation of the inspection report, the documents submitted with that report and pertinent documentation obtained from the sponsor, FDA's 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 new drugs and repeatedly or deliberately submitted false information in violation of FDA regulations (see Title 21, Code of Federal Regulations (CFR) Part 312.70 (enclosure #2)).

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 the sponsor, in violation of 21 CFR 312.70(a).

You signed the FDA Form 1572 on May 6, 1999, indicating your commitment as the principal investigator of record. You admitted in an affidavit signed by you on August 22, 2001, that you were solely responsible for the conduct of the study.

You admitted in the signed affidavit that:

- As the principal investigator and sole individual responsible for the conduct of this study, you submitted the following false information:

  On or about August 11, 1999, you entered seven fictitious subjects identified as B007, [ ]B008,[ ]B009,[ ]B010,[ ]B011,[ ]B012,[ ](a screening failure); and B013, MRM into the study through the sponsor's telephonic interactive voice response system (IVRS).

- Following the entry of these fictitious subjects into the study, you fabricated all of the records associated with these subjects. The falsified records included, but were not limited to, forged consent forms and completed case report forms (including inclusion/exclusion criteria, questionnaires, osteoarthritis diagnoses, vital signs, concomitant medications, drug inventories, and serious adverse events). In addition, you fabricated telephone contact information with these subjects and medical information related to their subsequent visits.

- You knowingly and willingly submitted blood and urine samples, supposedly from these subjects, for analysis by[ ]You generated these samples from surplus specimens obtained from patients from your clinical practice.

2. **You failed to conduct the study according to the approved protocol, in violation of 21 CFR 312.60.**

   You admitted in the signed affidavit that you created subjects and misrepresented the protocol-required clinical data, and that the study drug for these subjects was destroyed on site and never administered to any subject.

3. **You failed to prepare and maintain adequate and accurate case histories, in violation of 21 CFR 312.62.**

   You failed to maintain all pertinent study records for certain subjects. When questioned about the source data for these subjects, you declined to submit this information to the sponsor, and stated in your affidavit that you then destroyed all related records.

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 alleges that you have repeatedly or deliberately submitted false information and 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, HFD-45
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 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 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 (enclosure #3).

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 (enclosure #1) and 21 CFR 312.70 (enclosure #2). 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,

Joanne L Rhoads M.D.

Joanne L. Rhoads, M.D., MPH
Director
Division of Scientific Investigations, HFD-45
Office of Medical Policy
Center for Drug Evaluation and Research

Enclosures:
#1- 21 CFR Part 16
#2- 21 CFR Part 312.70
#3- Consent Agreement