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)

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Maria Anne Campbell
aka Anne Kirkman Campbell, M.D.
c/o FMC LEXINGTON
SATELLITE CAMP
P.O. BOX 14525
Lexington, Kentucky 40512

Dear Dr. Campbell:

Between October 15 and 24, 2002, Ms. Patricia S. Smith, representing the Food and Drug Administration (FDA), conducted an investigation and met with you to review your conduct of the following clinical study:

> Protocol [ ] entitled "Randomized, Open-Label, Multicenter Trial of the Safety and Effectiveness of Oral Telithromycin (Ketek®) and Amoxicillin/Clavulanic Acid (Augmentin®) in Outpatients with Respiratory Tract Infections in Usual Care Settings." This study of the investigational drug telithromycin was performed for Aventis Pharmaceuticals, Inc.

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 participating in clinical research have been protected. At the conclusion of the inspection, Ms. Smith presented and discussed with you the items listed on the Form FDA 483, Inspectional Observations.

FDA's October of 2002 inspection raised numerous concerns with your conduct of this study, including potential fabrication of study subjects, fabrication of study data, and enrollment of ineligible subjects. The FDA Field Investigator referred the matter to FDA's Office of Criminal Investigations (OCI) for further investigation. OCI's investigation determined that you falsified Case Report Forms (CRFs) that were submitted to the sponsor and falsified documentation to support the existence of a fictitious subject. A federal grand jury returned a 21 count criminal indictment on August 29, 2003. On October 23, 2003, you pled guilty to a single count of the indictment to resolve all the charges, admitting you used the mail in furtherance of a scheme to defraud by submitting a CRF to [ ] (the contract research organization retained by the sponsor to conduct the study) for a subject who did not exist (subject #26). You were sentenced on March 24, 2004 to 57 months in prison, fined

$557,251.22, given 3 years supervised release after your prison term is served, and ordered to make restitution to Aventis Pharmaceuticals in the amount of $925,774.61. This letter provides you with written notice of the matters under complaint by FDA and initiates an administrative proceeding, described below, to determine whether you should be disqualified from receiving investigational drugs as set forth under 21 CFR 312.70 (copy enclosed).

Based on our evaluation of the plea agreement, the federal grand jury indictment, the inspection report, the documents submitted with the report, information obtained from OCI's investigation, other pertinent information obtained by the Agency, and your November 4, 2002 response to the Form FDA 483, we believe you submitted false information in a required report to FDA or the sponsor, in violation of 21 CFR 312.70(a), and FDA proposes that you be disqualified as a clinical investigator.

Between November 7, 2001 and March of 2002, you completed CRFs for 407 subjects purportedly enrolled in the above-referenced study. The CRFs were submitted to the sponsor and reflected the enrollment of the subjects and their participation in the study. In the course of its investigation, however, OCI gathered evidence that over 200 subjects purportedly enrolled in this study had not, in fact, participated in it, and that one subject (#26) did not exist.

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

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. 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 if you wish to arrange a conference time or to indicate your intent to respond in writing.

Should you choose 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:

Joseph Salewski
Acting 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 provide all pertinent

documents, and a representative of your choice 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 products. Such an agreement would terminate this disqualification proceeding. We have received your letter of January 20, 2006, in which you indicate your "voluntary withdrawal status to participate in any clinical research studies now or in the future." If, as your letter suggests, you wish to voluntarily agree to be disqualified as a clinical investigator, you may enter into a consent agreement with FDA to do so. Enclosed you will find a proposed agreement.

The FDA's Center for Drug Evaluation and Research (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. 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,

{See appended electronic signature page}

Joseph Salewski
Director (Acting)
Division of Scientific Investigations, HFD-45
Office of Medical Policy
Center for Drug Evaluation and Research

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

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Leslie Ball
5/18/2006 09:58:43 AM
LKB acting for Joseph Salewksi