DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NOTICE OF OPPORTUNITY FOR HEARING (NOOH)

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

DEC 2 1 2007

Maria Anne Kirkman Campbell, M.D.
c/o FMC LEXINGTON
SATELLITE CAMP
P.O. BOX 14525
Lexington, Kentucky 40512-4525

Dear Dr. Campbell:

The Center for Drug Evaluation and Research (the Center) of the Food and Drug Administration (FDA) has information indicating that you repeatedly or deliberately submitted false information to FDA or the sponsor in a required report. This provides the basis for withdrawal of your eligibility as a clinical investigator to receive investigational new drugs. Please note that, as previously explained, this disqualification proceeding is distinct from the additional administrative proceeding in which FDA has proposed to debar you from providing services to drug applicants.[1]

The Center's findings are based on information relating to your conduct as an investigator for 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.

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[1] In his letter to you dated April 5, 2007, Gary Della'Zanna, then Director of the Division of Scientific Investigations within the Center's Office of Compliance, explained what it means to be disqualified and debarred by FDA and under what circumstances the agency may take these actions. The nature and bases for each of these two actions was also explained at the April 9, 2007 informal conference discussed below, as well as in agency correspondence to you relating to the disqualification and debarment proceedings, respectively.

Pursuant to section 312.70(a) of Title 21 of the Code of Federal Regulations [21 CFR 312.70(a)], the Center informed you, by letter titled "Notice of Initiation of Disqualification Proceedings and Opportunity to Explain" (NIDPOE) dated May 18, 2006, of numerous concerns with your conduct of this study, including potential fabrication of study subjects, fabrication of study data, and enrollment of ineligible subjects, as described below.

Between October 15 and 24, 2002, FDA, conducted an investigation and met with you to review your conduct of this clinical study. 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. Specifically, between November of 2001 and March of 2002, you completed CRFs for 407 subjects purportedly enrolled in the study. The CRFs were submitted to the sponsor, Aventis, 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 —— did not exist.

A federal grand jury returned a 21-count criminal indictment against you on August 29, 2003 for devising a scheme to defraud Aventis and[ ]the contract research organization retained by Aventis to conduct the study) by submitting false documentation to them, and for using the mail in furtherance of this scheme, in violation of 18 USC 1001(a), 1341, and 1342. Among other things, these charges alleged your submission of fraudulent CRFs that reflected: (1) enrollment of people as study subjects who did not qualify under the study protocol; (2) enrollment of a non-existent person; (3) having informed study subjects of their participation in the study and their having consented to participate when they had not been so informed and had not consented to participate; (4) examination of subjects and their being diagnosed with a qualifying disease when such examination and diagnosis had not occurred; (5) submittal of blood samples for analysis that were not actually drawn from the identified subjects on the dates stated; (6) substitution of blood drawn from another person for that of a study subject; and (7) return of subjects for follow-up visits and completion of the study when the subjects had not returned and had not completed the study. In addition, as part of your scheme to defraud, you were charged with receiving via the mail several checks from[ ]constituting payments for conducting the clinical study on Ketek.

On October 22, 2003, you pled guilty to a single count of the indictment to resolve all the charges. You admitted that you used the mail in furtherance of a scheme to defraud by submitting a CRF to[ ]for a subject who did not exist (subject —— 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.

The NIDPOE offered you an opportunity to respond in writing or at an informal conference. It also offered you the option of entering into a consent agreement with FDA (the proposed Agreement with Respect to Use of Investigational Products (Agreement)),

thereby terminating this disqualification proceeding against you. You responded to the NIDPOE with a letter dated June 12, 2006. In your response you expressed willingness to attend an informal conference with FDA regarding the disqualification proceedings.

An informal conference was held by telephone with you and representatives from FDA on April 9, 2007. In this conference, we explained the disqualification process and offered you an opportunity to ask questions and to make any arguments, in addition to those you had previously made in writing, for why the disqualification process should not proceed. You offered no additional arguments. In addition, we explained your opportunity to request a hearing regarding your disqualification. We also reviewed the content of the Agreement with you, and you requested certain changes to it.

On May 22, 2007 the FDA provided to you a revised version of the Agreement (revised Agreement), incorporating those proposed changes that FDA has found acceptable. In addition, FDA provided you an explanation regarding each of your proposed changes that FDA did not accept. We also requested that you notify us in writing no later than fifteen (15) days from the date of receipt of the revised Agreement regarding your intent to sign or not to sign it.

In a letter dated May 23, 2007, you wrote to FDA, apparently to request additional time to consider whether to enter into the revised Agreement, so that you might have a lawyer review it. In a letter dated July 2, 2007, FDA responded, stating our intent to proceed with the next stage of the disqualification proceedings without further delay, and explaining that we were, therefore, currently preparing an NOOH. We also explained that issuance of the NOOH would not preclude you from subsequently entering into a consent agreement with FDA. We asked you to have your lawyer contact us by July 31, 2007, regarding your intentions to sign the revised Agreement or to request a hearing, and that you contact us directly by that date regarding your intentions if you did not obtain legal counsel.

You responded to our letter of July 2, 2007, with a letter dated July 17, 2007. In the July 17 letter, you restated that you wish to obtain legal counsel on the matter, and asserted that you have been unable to do so while incarcerated. In a letter to you dated August 16 (regarding the separate administrative proceeding in which FDA has proposed to debar you from providing services to drug applicants), we noted that Federal prison regulations clearly provide inmates the opportunity to obtain and communicate with legal counsel while incarcerated (as described, for example, in the Federal Bureau of Prisons Program Statement 1315.07--Legal Activities, Inmate). You replied in a letter dated August 21, 2007, that the institution in which you are incarcerated "does not follow" these regulatory requirements.

We have contacted staff and legal counsel for your prison, and they have confirmed that, upon request, you may retain and communicate with a lawyer both by phone and in person, as provided for in Federal prison regulations; they have also informed us that you have made no such request to date. They have assured us that you may contact your case manager to arrange times both to call legal counsel and to meet with counsel privately at the prison, and such arrangements should be able to be made within a few days of the

request. It bears noting in this regard that restrictions applicable to other outside communications, for example, with regard to phone time per month and length of phone calls, do not apply to communications with legal counsel.

Also, they have informed us that Legal Aid comes to the prison weekly and that you can arrange to meet with representatives of this organization by submitting an inmate request. We understand that Legal Aid may be able to assist you in obtaining legal counsel if they are not able to represent you themselves.

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, your November 4, 2002 response to the Form FDA 483, and the informal conference, we believe you repeatedly or deliberately submitted false information in a required report to FDA or the sponsor. Therefore, in accordance with 21 CFR 312.70, FDA proposes that you be disqualified as a clinical investigator entitled to receive investigational drugs. Therefore, we are offering you the opportunity for a regulatory hearing before FDA, pursuant to 21 CFR 16 and 21 CFR 312, to determine whether you will remain entitled to receive investigational new drugs. A presiding officer free from bias or prejudice and who has not participated in this matter will conduct the hearing.

You have the right to be advised and represented by counsel at all times. Any regulatory hearing on this matter will be governed by the regulations in 21 CFR part 16 and FDA's guidelines on electronic media coverage of administrative proceedings, 21 CFR part 10, subpart C. Enclosed you will find copies of these regulations. The basis for disqualification under 21 CFR 312.70(a) as described above will be considered at the regulatory hearing.

Your request for a hearing must be made, in writing, and should be directed to Fredric J. Richman, Director, Division of Compliance Management and Operations (HFC-210), Office of Enforcement, ORA, FDA, 15800 Crabbs Branch Way, Rockville, MD 20855, Telephone (240) 632-6862, FAX (240) 632-6859.

In case there has been any confusion to date with regard to your options for legal representation, FDA is granting you thirty (30) days after receipt of this letter to request a hearing, rather than the standard ten (10) days. We are granting you this additional time to enable you to retain legal counsel if you still wish to do so, before deciding whether to request a hearing. If no response to this letter is received by the end of this thirty-day period, you will be deemed to have waived any right to a regulatory hearing, and a decision in these matters will be made based on the facts available to FDA. No hearing will be held.

A request for a hearing may not rest upon mere allegations or denials, but must present specific facts showing that there is a genuine and substantial issue of fact that warrants a hearing. Pursuant to 21 CFR 16.26, a request for a hearing may be denied, in whole or in part, if the Commissioner or his delegate determines that no genuine and substantial issue

of fact has been raised by the material submitted. A hearing will not be granted on issues of policy or law. Written notice of a determination of summary judgment will be provided, explaining the reasons for denial of the hearing.

If you wish to respond, but do not desire a hearing, you should send a written response to Mr. Richman within the time period specified above containing your reply. The letter should state that you waive your right to a hearing and that you want a decision on the matter to be based on your written response and other information available to FDA. FDA's offer to enter into the Agreement, attached to the NIDPOE letter dated May 18, 2006, or into the revised Agreement provided to you on May 22, 2007, also remains available. Entering into a consent agreement would terminate the disqualification procedures, but would not preclude the possibility of a corollary judicial proceeding. If you wish to enter into a consent agreement, you should send a written response to Mr. Richman stating this wish within the time period specified above.

No final decision by FDA has been made at this time on your eligibility to continue to receive investigational new drugs. Moreover, there will be no prejudgment of this matter if you decline to enter into a consent agreement and decide instead either to request a regulatory hearing or to request that the decision be based on information currently available to FDA.

Please inform Mr. Richman within thirty (30) days after receipt of this letter of whether you wish to request a hearing or to have this matter resolved by consent agreement or information available to FDA.

Sincerely,

Margaret O'K. Glavin
Associate Commissioner
for Regulatory Affairs

Enclosures:
21 CFR 312.70
21 CFR part 10, subpart C
21 CFR part 16

cc: [ ] Unit Manager