DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

- 8 MAY 2008

By Certified Mail - Return Receipt Requested

Maria Anne Kirkman Campbell, M.D.
c/o CCM MONTGOMERY
COMMUNITY CORRECTIONS OFFICE
GUNTER ANNEX BLDG834
105 S TURNER BLVD
MAXWELL AFB, AL 36114

Notice of Disqualification to Receive Investigational New Drugs

Dear Dr. Kirkman Campbell:

On December 21, 2007, the Food and Drug Administration (FDA) sent you a Notice of Opportunity for a Hearing (NOOH, attached), pursuant to 21 CFR § 16.22 and § 312.70, to determine whether you would remain entitled to receive investigational new drugs. In your response to the NOOH dated January 13, 2008, you did not request a hearing. FDA considers this to be a refusal of the offer for a hearing and, therefore, no hearing will be held [21 CFR § 16.22(b)].

On the basis of all information available to FDA, I have determined that you have repeatedly or deliberately submitted false information in a required report to FDA or the sponsor in violation of 21 CFR 312.70. These violations occurred in the following clinical study sponsored by Aventis Pharmaceuticals, Inc.:

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."

In accordance with 21 CFR Parts 16 and 312.70, you are hereby advised that you are no longer entitled to receive investigational new drugs.

FDA will notify the sponsor of the clinical studies of investigational new drugs in which you participated as an investigator that you are no longer entitled to receive investigational products. The notifications will include the basis for your disqualification, and the steps the sponsors should take.

FDA will make this notice available to interested parties under the Freedom of Information Act (FOIA). Your name will also be added to the list of clinical investigators who have been disqualified that is available under FOIA and posted on FDA's Internet website.

Sincerely,

Andrew C. von Eschenbach, M.D.
Commissioner of Food and Drugs

Attachment - Copy of NOOH to Dr. Kirkman Campbell, dated December 21, 2007