DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

DEC 11 2009

By Certified Mail - Return Receipt Requested

Kim C. Hendrick, M.D.
Flushing Family Care PC and
Flushing Research Center PC
6429 West Pierson Road, Suite 12
Flushing, Michigan 48433

Notice of Disqualification to Receive Investigational New Drugs

Dear Dr. Hendrick:

On July 1, 2009, FDA sent you a Notice of Opportunity for a Hearing (NOOH, enclosed), pursuant to Title 21, Code of Federal Regulations (CFR) Sections 16.22 and 312.70, to determine whether you would remain eligible to receive investigational new drugs. You confirmed that you received the NOOH by signing the Confirmation of Receipt of Notice of Opportunity for Hearing (NOOH) letter on July 1, 2009.

The NOOH explained three options for you to resolve this matter; namely, to request a hearing, to submit additional written information for FDA's consideration, or to enter into a consent agreement. The NOOH detailed the content of the written response that you must make if you wished to exercise one of these options. It also stated that you must submit that response within ten (10) business days after receipt of the letter.

As of October 22, 2009, no response to the NOOH dated July 1, 2009 has been received by FDA from you or your attorney. Pursuant to FDA regulations, the failure to respond within the time specified in the NOOH is deemed a refusal of the offer for a hearing. Where there has been no response to the NOOH, no hearing shall be held [21 CFR 16.22(b)].

On the basis of all information available to FDA, I have concluded that you repeatedly or deliberately violated 21 CFR Part 312 in your capacity as an investigator in clinical investigations of the investigational new drugs Augmentin SR, Oral SB-265805, and Oral Cefuroxime Axetil, and repeatedly or deliberately submitted false information in a required report to FDA or the sponsor in violation of 21 CFR 312.70. Consistent with 21 CFR 312.70(b), and under authority delegated to me by the Commissioner of Food and Drugs, you are hereby advised that you are no longer eligible to receive investigational new drugs.

FDA will notify the sponsors of the clinical studies of investigational new drugs in which you participated as an investigator that you are no longer eligible 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 website.

You may seek to have your eligibility to receive investigational new drugs reinstated, pursuant to 21 CFR 312.70(f), upon presentation of adequate assurances that you will employ investigational new drugs solely in compliance with the provisions of 21 CFR Parts 50, 56, and 312.

Sincerely,

Norris E. Alderson, Ph.D.
Associate Commissioner for Science

Enclosure: Copy of NOOH to Kim C. Hendrick, M.D., dated July 1, 2009

cc: Seth Ray, Esq.
Counsel for the Center for Drug Evaluation and Research