



Mukesh Kumar, Ph.D., RAC
Senior Director
Regulatory Affairs
Amarex, LLC
20201 Century Blvd
Suite 450
Germantown, MD 20874

FEB 23 2010

Dear Dr. Kumar:

The purpose of this letter is to inform you that the Food and Drug Administration (FDA) inspection conducted at your clinical research organization (CRO) site on January 11, 2010, revealed no significant concerns.

The inspection was conducted by an investigator from FDA's Baltimore District Office and covered your CRO's activities in FDA-regulated research. We appreciate the courtesy and cooperation extended to the FDA investigator during the inspection and subsequent closeout discussion. No response is necessary at this time.

You may find information concerning the device Bioresearch Monitoring program at our Internet homepage. Valuable links to related information are also included at this site. <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/BioresearchMonitoring/default.htm> The Division of Bioresearch Monitoring has developed introductory training modules in FDA regulated device clinical research practices, which are available on the FDA website. The modules are for persons involved in FDA regulated device clinical research activities. These modules are located at the following website address: <http://www.fda.gov/Training/CDRHLearn/ucm162015.htm> If you have any questions, do not hesitate to contact Adam Donat at main line (301) 796-5490, or direct (301) 796-5316.

Sincerely yours,

Linda D. Godfrey
Acting Chief
Program Enforcement Branch B
Division of Bioresearch Monitoring
Office of Compliance
Center for Devices and
Radiological Health