



OCT 28 2005

Food and Drug Administration
Center for Devices and
Radiological Health
2098 Gaither Road
Rockville, MD 20850

George S. Schuster, DDS, Ph.D.
Chairman
Medical College of Georgia Human
Assurance Committee
1120 15th Street, Room CJ 2103
Augusta, Georgia 30912

Dear Dr. Schuster:

The purpose of this letter is to inform you that the Food and Drug Administration (FDA) inspection conducted at your site revealed no significant deviations from the FDA regulations governing investigational devices and/or human research subject protection. An investigator from FDA's Atlanta District Office conducted the inspection during the period of September 14 through September 16, 2005. The purpose of the inspection was to determine if your activities as an Institutional Review Board (IRB) complied with Title 21, Code of Federal Regulations (21 CFR) Part 50 – Protection of Human Subjects; 21 CFR, Part 56 – Institutional Review Boards; and Part 812 – Investigational Device Exemptions. These regulations apply to the research of FDA-regulated products.

No observations were noted during the inspection, and no Form FDA 483 "Inspectional Observations" was issued at the conclusion of the inspection.

No further response is necessary at this time. We appreciate the courtesy and cooperation extended to the FDA investigator during the inspection and subsequent closeout discussion. In addition, you may find information concerning the device Bioresearch Monitoring program at our Internet homepage, <http://www.fda.gov/cdrh/comp/bimo.html>. Valuable links to related information are also included at this site. If you have further questions, please feel free to contact Patricia L. Jahnes at (240) 276-0125.

Sincerely yours,

Viola Sellman
Chief, Program Enforcement Branch
Division of Bioresearch Monitoring
Office of Compliance
Center for Devices and
Radiological Health