DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

M33521

Via Federal Express

JAN 28 2000

WARNING LETTER

Charles H. Williamson, M.D.
Williamson Eye Center
550 Connell's Park Lane
Baton Rouge, Louisiana 70806

Dear Dr. Williamson:

During the period of November 1 through November 12, 1999, you were visited by Barbara D. Wright, an investigator from the Food and Drug Administration's (FDA) New Orleans District Office. The purpose of Ms. Wright's visit was to determine whether your activities and procedures as a clinical investigator for the [redacted] study sponsored by [redacted] Company, complied with applicable regulations. This product is a device as that term is defined under Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

This inspection was conducted under a program designed to ensure that data and information contained in applications for Investigational Device Exemptions (IDE), Premarket Approvals (PMA), and Premarket Notification [510(k)] submissions are scientifically valid and accurate. Another objective of the program is to ensure that human subjects are protected from undue hazard or risk during the course of the scientific investigation.

We have completed our review of the inspection report submitted by the New Orleans District Office. The report reveals significant violations of the requirements under Title 21, Code of Federal Regulations (21 CFR), Part 50 - Protection of Human Subjects; 21 CFR Part 56 - Institutional Review Boards; and 21 CFR Part 812 - Investigational Device Exemptions. These violations were listed on the Form FDA 483, "Inspectional Observations," which was presented to and discussed with you at the conclusion of the inspection. The deviations noted on the Form FDA 483 and our subsequent review of the inspection report are summarized below:

Failure to provide study subjects with the basic elements of informed consent *(21 CFR 50.25(a)(7)).*

You failed to provide study subjects with essential information necessary for informed consent. For example, the informed consent form used for the [redacted] study through February 17, 1997, did not include an explanation of whom to contact for answers to pertinent questions about the research and study subjects' rights, and whom to contact in the event of a research-related injury to the subject.

Failure to maintain investigator records relating to participation in an investigation *(21 CFR 56.109(f) and 812.140(a)(1)).*

You failed to maintain investigator records showing continuing review by an institutional review board (IRB) of research covered by the Federal regulations. For example, the initial IRB approval of the [redacted] study is dated [redacted] After this date, no other records are available to show continuing IRB review of the [redacted] study.

Failure to conduct an investigation in accordance with the investigational plan *(21 CFR 812.100).*

You failed to adhere to the document entitled, "Investigational Plan and Report of Prior Investigations [redacted] for Investigational Review Boards and Investigators," [redacted] For example, the following deviations from the investigational plan were noted:

- No case report forms (CRFs) have been completed since August 12, 1998, even though the investigational plan calls for annual follow-up visits of study subjects through May 15, 2000;
- Almost one-fifth of the post-operative CRFs reviewed were completed in error for the timeframe specified;
- In six (6) instances, [redacted] were not obtained for a time period defined in the investigational plan as a "primary measure of efficacy;" and
- Inaccurate reporting on CRFs of complications found during the postoperative evaluation occurred in thirteen (13) instances.

Failure to maintain accurate, complete, and current records relating to your participation in an investigational study *(21 CFR 812.140(a)(3)).*

You failed to maintain accurate, complete, and current records relating to your participation in an investigational study including CRFs and supporting data. For example, data reporting errors were noted in more than ten percent (10%) of the CRFs reviewed. The errors include incorrect reporting on CRFs of [redacted] results and [redacted] for study subjects.

The deviations listed above are not intended to be an all-inclusive list of deficiencies at your site. As a clinical investigator, it is your responsibility to ensure that investigations that you participate in are conducted in accordance with applicable FDA regulations. To assist you, we have enclosed a copy of the *FDA Information Sheets,* guidance for clinical investigators.

Please advise this office, in writing, **within fifteen (15) working days of receipt of this letter** of the specific steps you have taken to correct these violations and other violations known to you, and to prevent the recurrence of similar violations in current or future studies. Failure to respond can result in further regulatory action, including disqualification, without additional notice.

You should direct your response to the Food and Drug Administration, Center for Devices and Radiological Health, Office of Compliance, Division of Bioresearch Monitoring, Program Enforcement Branch II (HFZ-312), 2098 Gaither Road, Rockville, Maryland 20850, Attention: Kathleen E. Swisher, R.N., J.D., Consumer Safety Officer.

A copy of this letter has been sent to our New Orleans District Office, 6600 Plaza Drive, Suite 400, New Orleans, Louisiana 70127. We request that a copy of your response be sent to that office as well.

Sincerely yours,

for Lillian J. Gill
Director
Office of Compliance
Center for Devices and
Radiological Health

Enclosure

cc: Greg Roth, President
Columbia Healthcare Corporation
Ambulatory Surgery Division
13455 Noel Road
21st Floor
Dallas, Texas 75240