



m3433n

Via Federal Express

Food and Drug Administration  
2098 Gaither Road  
Rockville MD 20850

FEB 25 2000

**WARNING LETTER**

Nicholas A. Crefasi  
Administrator  
Outpatient Surgery Center for Sight  
Institutional Review Board  
550 Connell's Park Lane  
Baton Rouge, Louisiana 70806

Dear Mr. Crefasi:

During the period of November 10 through November 12, 1999, Barbara D. Wright, an investigator from the Food and Drug Administration's (FDA) New Orleans District Office visited the Outpatient Surgery Center for Sight Institutional Review Board (IRB). The purpose of Ms. Wright's visit was to conduct an inspection to determine whether the IRB's activities and procedures involving the protection of human subjects participating in clinical studies of FDA-regulated products complied with applicable FDA regulations. The inspection focused on the [REDACTED] sponsored by [REDACTED] and conducted at The Williamson Eye Center also known as the Outpatient Surgery Center for Sight, Inc.

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 56 - Institutional Review Boards; 21 CFR Part 50 - Protection of Human Subjects; and 21 CFR Part 812, Subpart D - IRB Review and Approval. 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 maintain and follow written procedures for IRB functions and operations (21 CFR 56.108 and 812.60).**

You failed to maintain and follow written procedures relating to the IRB's performance. For example, no written IRB procedures are available as required by FDA regulations for the IRB's continuing review of an investigation. Specifically, no written procedures are available for the following:

- reporting the IRB's findings and actions to the investigator and the institution;
- determining which projects require review more often than annually and which projects need verification from sources other than the investigator that no material changes have occurred since previous IRB review;
- ensuring prompt reporting to the IRB of changes in research activity;
- ensuring that changes in approved research, during the period for which IRB approval has already been given, may not be initiated without IRB review and approval except where necessary to eliminate apparent immediate hazards to the human subjects; and
- ensuring prompt reporting to the IRB, appropriate institutional officials, and the FDA of any unanticipated problems involving risks to human subjects or others, any instance of serious or continuing noncompliance with the regulations or the requirements or determinations of the IRB, or any suspension or termination of IRB approval.

The absence of written procedures precluded the IRB's adherence to written procedures in accordance with the regulations.

**Failure to prepare and maintain records of the IRB composition, duties, functions, and activities (21 CFR 56.115 and 812.60).**

You failed to prepare and maintain adequate documentation of IRB activities. For example, no documentation is available of the following:

- IRB members identified by name, earned degrees, representative capacity, indications of experience, and any employment or other relationship between each member and the institution;
- minutes of IRB meetings showing attendance, actions taken, voting results, rationale for IRB required changes to research, and a summary of controverted issues discussed and their resolution(s); and
- research proposals reviewed, approved sample consent documents, progress reports submitted by investigators, and reports of injuries to subjects.

FDA regulations require that IRBs maintain documentation of their activities for at least three (3) years after completion of the research, and that the records be accessible for inspection and copying by authorized FDA representatives.

The deviations listed above are not intended to be an all-inclusive list of deficiencies at your site. As an IRB, it is your responsibility to ensure that investigations that you approve are conducted in accordance with applicable FDA regulations. To assist you, we have enclosed a copy of the *FDA Information Sheets, Guidance for Institutional Review Boards and Clinical Investigators*.

Please advise this office, in writing, **within fifteen (15) working days of receipt of this letter** of the specific steps that 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 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. The adequacy of your corrective actions may be confirmed during a future FDA inspection.

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  
21<sup>st</sup> Floor  
Dallas, Texas 75240



Williamson Eye Center  
550 Connell's Park Lane  
Baton Rouge, Louisiana 70806

Michael Carome, M.D.  
National Institutes of Health  
Office for Protection from Research Risks  
Compliance Oversight Branch, MSC 7507  
6100 Executive Blvd, Suite 3B01  
Rockville, MD 29892-7501