

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

FEB 25 2000

WARNING LETTER

Via Federal Express

C. Joseph Anderson, M.D.
Anderson & Shapiro Eye Care
1200 John Q. Hammons Drive, Suite 100
Madison, Wisconsin 53717

Dear Dr. Anderson:

During the period of September 7 through September 29, 1999, Mr. Ronald R. Ruff, an investigator from the Food and Drug Administration's (FDA) Minneapolis District Office, visited you. The purpose of Mr. Ruff's visit was to determine whether your activities and procedures as a clinical investigator for the [REDACTED] sponsored by [REDACTED] and conducted by you while associated with [REDACTED] complied with applicable regulations. This product is a device as that term is defined in section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

The inspection revealed that you are no longer associated with [REDACTED] and as of February 1998 you discontinued participation in the [REDACTED]. However, since the inspection focused on the time period that you were responsible for the study, the FDA investigator visited you at your new location and also visited [REDACTED] who now has custody of the records.

The inspection was conducted under a program designed to ensure that data and information contained in requests for Investigational Device Exemptions (IDE), Premarket Approval Applications (PMA), and Premarket Notifications [510(k)] 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 scientific investigations.

We have completed our review of the inspection report submitted by the Minneapolis District Office. The report revealed significant deviations from the requirements of Title 21, Code of Federal Regulations (21 CFR), Part 812 - Investigational Device Exemptions and 21 CFR Part 50 - Protection of Human Subjects. The deviations noted during the inspection were listed on the Form FDA-483 "Inspectional Observations" (copy enclosed), which was presented to and discussed with [REDACTED] at the conclusion of the inspection. The deviations noted and our subsequent review of the inspection report are summarized below.

Failure to maintain accurate, complete, and current records as required by 21 CFR 812.140(a)(1), (2), and (3)(ii).

You failed to maintain records relating to your participation in an investigational study including documentation of IRB approval and continuing review; records of receipt and final disposition of investigational devices; and a record of the subject's case history and exposure to the device. In addition, you did not maintain a copy of the study protocol.

In reference to the subject's case history and exposure to the device, you did not maintain case report forms and the patient medical chart for study [REDACTED]. Data supplied by the sponsor indicated that this patient discontinued the study due to death. You did not document this in your records. Further, case report form [REDACTED] reported that "patient" [REDACTED], you did not document the cause of death.

As a clinical investigator, you are responsible for documenting each subject's case history and exposure to the device including adverse device effects (whether anticipated or unanticipated), information and data on the condition of each subject upon entering, and during the course of the investigation. In addition, you are responsible for maintaining study records during the investigation and for a period of 2 years after the investigation is terminated or completed, or the date that the records are no longer required for purposes of supporting a premarket approval application or a notice of completion of a product development protocol.

Failure to provide FDA with a notice of transfer of record custody within ten (10) working days after the transfer occurred (21 CFR 812.140(e)).

You failed to prepare and submit to FDA, within ten (10) working days, a notice of transfer of record custody. For example, your records did not include any notification to the IRB and sponsor, or agreement with the sponsor, concerning a change in the participating investigator and transfer of custody of records to [REDACTED]

Failure to obtain and provide an adequate informed consent (21 CFR 50.20).

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

Failure to prepare and submit complete, accurate, and timely reports as required by (21 CFR 812.150(a)(3)).

You failed to submit progress reports to the sponsor, monitor, and IRB at regular intervals.

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.

Please send 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: Pamela Reynolds. A copy of this letter has been forwarded to our Minneapolis District Office, 240 Hennepin Avenue, Minneapolis, Minnesota 55401. We request that a copy of your request be sent to that office as well.

Sincerely yours,

Pamela Reynolds, R.Ph.

for

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

Enclosures: Copy of Establishment Inspection Report
FDA Information Sheets

cc:

[Redacted]