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Via Federal Express

DEC 11 2003

WARNING LETTER

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

Joseph P. Corcoran
President/CEO
New York Eye and Ear Infirmary
310 East 14th Street
New York, New York 10003

Dear Mr. Corcoran:

The purpose of this Warning Letter is to inform you of objectionable practices and activities found during a Food and Drug Administration (FDA) inspection of the New York Eye and Ear Infirmary, Institutional Review Board, which serves as the IRB for your institution, and to request corrective actions. The inspection took place during the period of July 17 through 23, 2003, and was conducted by Thomas P. Hansen, an investigator from FDA's New York District Office.

The purpose of the inspection was to determine whether your activities and procedures as an IRB complied with Title 21, Code of Federal Regulations (21 CFR), Part 50 - Protection of Human Subjects, Part 56 - Institutional Review Boards, Part 812 - Investigational Device Exemptions and Part 814 - Premarket Approval of Medical Devices. These regulations apply to clinical studies of products regulated by the FDA.

Our review of the information contained in the establishment inspection report prepared by the district office revealed serious violations of governing regulations. At the conclusion of the inspection Investigator Hansen listed the observations on the Form FDA 483, "Inspectional Observations," which was presented and discussed with Dr. Joseph B. Walsh, IRB Chairman and Mr. Robert O. Jordan, IRB Administrator.

Listed below is a description of the violations from the regulations:

Failure to maintain meeting minutes in sufficient detail (21 CFR 56.115(a)(2)).

FDA regulations require IRB activities to be adequately documented. The minutes of IRB meetings must be in sufficient detail to show the attendance at the meeting, actions taken, the specifics of who votes and how, the basis for requiring changes in disapproving research, and a written summary of the discussion of controverted issues and their resolution. Your IRB meeting minutes lacked a summary of discussion, actions taken by the IRB and the votes of these actions including the number of members voting for, against or abstaining. The minutes also failed to document that a determination was made of whether studies involved significant or non-significant risk devices and the frequency of periodic review for each study.

Failure to have adequate written procedures for the initial and continuing review of research as required by (21 CFR 56.108(a) & (b), 812.66 and 50.24).

The IRB must have and follow written procedures that describe the IRB's functions and operations. The IRB policy "The New York Eye & Ear Infirmary IRB Standard Operating Procedures" (January 1996) and "The New York Eye & Ear Infirmary Institutional Review Board" (May 2002), do not meet the FDA requirements for written procedures (i.e., how the process is accomplished) in several areas. The procedures that should be added or revised include, but are not limited to those discussed in this section.

- There are no procedures for reviewing reports of emergency use of a test article.
- Procedures do not address how adverse events are handled or the timeframes under which Serious Adverse Events (SAEs) are reported.
- The procedures do not address that the IRB has authority to suspend or terminate IRB approvals of research and will ensure prompt reporting of suspension or termination of IRB approvals to the appropriate institutional officials, and the appropriate governmental entity.
- Initial review procedures do not address how to determine whether an investigation involves a significant or non-significant risk device and how often continuing review will take place.

Failure to have a majority of IRB members present when reviewing and approving research studies (21 CFR 56.108(c)).

Inspectional findings revealed that at least nine (9) research studies were approved at meetings in which there was not a majority of IRB members present.

Failure to have at least one member on the IRB whose primary concerns are in nonscientific areas (21 CFR 56.107(c)).

Inspectional findings revealed that at multiple meetings the IRB failed to have a nonscientific member as part of the IRB board.

Failure to have a list of IRB members identified by name, earned degree and representative capacity (21 CFR 56.115(a)(5)).

The IRB membership list from 1998-2003 failed to show each member's earned degree, representative capacity, indications of experience such as board certifications and licenses, etc. In addition, we recommend that the membership list also identify the alternates' representation.

The deviations cited 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 participate in are conducted in accordance with applicable FDA regulations.

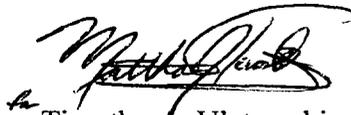
Within fifteen (15) days, you must respond to this letter in writing. You should be aware that FDA considers the IRB actions to be serious violations of the law and may result in FDA taking regulatory action without further notice. Failure to respond to this letter and to take prompt action to correct these violations may result in regulatory action without further notice, including disqualification of the IRB.

Please address your correspondence to the U.S. Food and Drug Administration, Center for Devices and Radiological Health, Office of Compliance, Division of Bioresearch Monitoring, Program Enforcement Branch I (HFZ-311), 2098 Gaither Road, Rockville, Maryland 20850, Attention: Rachel Solomon, Consumer Safety Officer.

A copy of this letter has been sent to FDA's New York District Office, 158-15 Liberty Avenue, Jamaica, New York, New York 11433. We request that a copy of your response also be sent to that office.

If you have any questions, feel free to contact Rachel Solomon at (301) 594-4720 extension 123.

Sincerely yours,



Timothy A. Ulatowski
Director
Office of Compliance
Center for Devices and
Radiological Health

Enclosure

cc:

Joseph B. Walsh, MD
IRB Chairman
New York Eye and Ear Infirmary
310 East 14th Street
New York, New York 10003