DEPARTMENT OF HEALTH & HUMAN SERVICES

New York District

Food & Drug Administration
300 Pearl Street, Suite 100
Buffalo, NY 14202

93182d

February 4, 2002

WARNING LETTER NYK 2002-22

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Sabina Raoof, M.D.
Chairman
Department of Radiology
Jamaica Hospital Medical Center
8900 Van Wyck Expressway
Jamaica, New York 11418

RE: Facility ID Number 182691

Dear Dr. Raoof:

Your facility was inspected on January 15, 2002 by a representative of the New York City Department of Health, acting on behalf of the Food and Drug Administration (FDA). This inspection revealed serious regulatory problems involving the mammography at your facility.

Under a United States Federal law, the Mammography Quality Standards Act of 1992, your facility must meet specific requirements for mammography. These requirements help protect the health of women by assuring that a facility can perform quality mammography. The inspection revealed the following repeat Level 2 finding at your facility:

- *Failed to produce documents verifying that the interpreting physician [redacted] met the continuing education requirement of having taught or completed at least 15 category 1 continuing medical education units in mammography in36 months.*

The specific problem noted above appeared on your MQSA Facility Inspection Report which was issued to your facility at the close of the inspection. This problem is identified as a repeat Level 2 because it identifies a failure to meet a significant MQSA requirement and it indicates a failure by your facility to implement permanent correction of a problem found during your previous inspection.

Because this condition may be symptomatic of serious underlying problems that could compromise the quality of mammography at your facility, it represents a violation of the law, which may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to, placing your facility under a Directed Plan of Correction, charging your facility for the cost of on-site monitoring, assessing civil money penalties up to $10,000 for each failure to substantially comply with, or each day of failure to substantially comply with MQSA standards, suspension or revocation of your facility's FDA certificate, or obtaining a court injunction against further mammography.

It is necessary for you to act on this matter immediately. Please explain to this office in writing within fifteen (15) working days from the date that you receive this letter each step your facility is taking to correct this violation and to prevent the recurrence of similar violations. Your response should include documents that demonstrate proper record keeping.

In addition, your response should address the Level 2 findings that were listed on the inspection report provided at the close of the inspection. The Level 2 findings are:

- ***Failure to perform the medical audit and outcome analysis for the facility as a whole.***
- ***Failure to perform the medical audit and outcome analysis separately for each individual physician at the facility.***
- ***Failure to perform the medical audit and outcome analysis annually.***

Please submit your response to the above issues to the attention of Lisa M. Utz, Compliance Officer, U.S. Food and Drug Administration, 300 Pearl Street, Suite 100, Buffalo, NY 14202, telephone (716) 551-4461 ext. 3117.

Finally, you should understand there are many FDA requirements pertaining to mammography. This letter pertains only to findings of your inspection and does not necessarily address other obligations you have under the law. You may obtain general information about all of FDA's requirements for mammography facilities by contacting the Mammography Quality Assurance Program, Food and Drug Administration, P.O. Box 6057, Columbia, Maryland 21045-6057 (1-800-838-7715), or through the Internet at http://www.fda.gov.

Sincerely,

Jerome G. Woyshner
District Director