DEPARTMENT OF HEALTH & HUMAN SERVICES 5173

New York District

Food & Drug Administration
158 - 15 Liberty Avenue
Jamaica, New York 11433-1034

WARNING LETTER

February 12, 2001

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

REF: NYK-2001-41

Ilona Hertz, MD
Radiologist
Beranbaum, Khilnani, Neistadt, Jacobs, Hertz & Sherman, MDs, P. C.
121 East 60th Street / 9th Floor
New York, New York 10022

Facility ID: #103036

Dear Dr. Hertz:

Your facility was inspected on January 2nd, 2001 by a representative of the New York City Department of Health, Bureau of Radiological Health, acting on behalf of the U. S. Food & Drug Administration (FDA). This inspection revealed serious regulatory problems involving the mammography operation at your facility. Under a United States Federal Law, the Mammography Quality Standards Act of 1992, your facility must meet specific requirements for mammography operations. These requirements help protect the health of women by assuring that a facility can perform quality mammography procedures. The inspection revealed the following Level 1 findings at your facility:

1. *The Phantom QC records for the [redacted] unit #4, were missing for twelve (12) weeks.*

2. *The Phantom QC records for the [redacted] unit #3, were missing for seven (7) weeks.*

The specific problems noted above appeared on your MQSA Facility Inspection Report, which was issued to your facility at the close of the inspection. These problems are identified as Level 1 because they identify failures to meet significant MQSA requirements. Because these conditions may be symptomatic of serious underlying problems that could compromise the quality of mammography operations at your facility, they represent 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 operations and practices.

There were also Level 2 noncompliance findings that were listed on the inspection report provided at the close of the inspection. The Level 2 noncompliance findings were:

1. *Corrective action before further exams, for a failing image score, or a Phantom background Optical Density, or Density difference outside the allowable regulatory limits, was not documented for both [redacted] unit #3 and the [redacted] unit #4.*

2. *The time period between the previous and current surveys for the [redacted], unit #3 & unit #4 exceeds fourteen (14) months.*

3. *Five (5) of five (5) random reports reviewed did not contain an Assessment Category for this site.*

It is necessary for you to act on these matters immediately. Please explain to this office in writing within fifteen (15) working days from the date you received this letter:

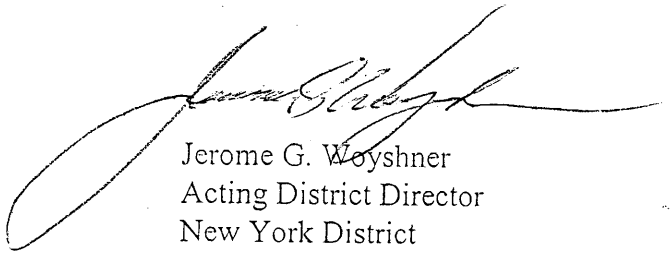
- *The specific steps you have taken to correct the violations noted in this letter;*
- *Each step your facility is taking to prevent the recurrence of similar violations; and*
- *Sample records that demonstrate proper record keeping procedures.*

Please submit your response to the above issues to the attention of Arthur S. Williams, Jr., Compliance Officer, U. S. Food & Drug Administration (FDA), 158 - 15 Liberty Avenue, Jamaica, New York 11433-1034, Tel.: (718)/662-5568.

Finally, you should understand there are many FDA requirements pertaining to mammography operations. This letter pertains only to findings of the 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 & Drug Administration, P. O. Box 6057, Columbia, Maryland 21045-6057 (!/800/838-7715), or through the Internet at *http://www fda. gov*.

Sincerely yours,



Jerome G. Woyshner
Acting District Director
New York District