



DEPARTMENT OF HEALTH & HUMAN SERVICES

M317M
New York District

Food & Drug Administration
850 Third Avenue
Brooklyn, NY 11232

WARNING LETTER

October 15, 1999

REF: NYK-2000-02

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Harvey Stern, M.D.
Director, Dept. of Radiology
Bronx Lebanon Hospital Center
1650 Grand Concourse
Bronx, New York 10457

Facility ID: 104737

Dear Dr. Stern:

We are writing to you because on September 8, 1999, your facility was inspected by a representative of the New York City Bureau of Radiological 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 findings at your facility:

- 1. The interpreting physician, [REDACTED], did not meet the continuing experience requirement of having read or interpreted 960 patient examinations in a 24 month period.*
- 2. As an interpreting physician, [REDACTED] also failed to meet the continuing experience requirement stated above.*

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 repeat Level 2 because they identify a failure to meet a significant MQSA requirement and indicate failure by your facility to implement permanent correction of problems found during your previous inspection.

Bronx Lebanon Hospital Center – Warning Letter NYK-2000-02

We note you responded last year that you had adjusted the schedule of interpretation to ensure that both [REDACTED] and [REDACTED] would meet the required number of examinations. Your letter also appears to contain an error in listing the number of required examinations as 460 rather than 960.

Because these conditions may be symptomatic of serious underlying problems that could compromise the quality of mammography 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.

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 you receive this letter:

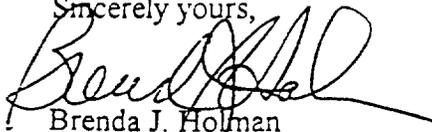
- the specific steps you have taken to correct the violation noted in this letter, and
- each step your facility is taking to prevent the recurrence of similar violations.

Please submit your response to the attention of Lillian C. Aveta, Compliance Officer, U.S. Food and Drug Administration, 850 Third Avenue, Brooklyn, New York 11232, Tel. (718) 340-7000, ext. 5142.

Finally, you should understand there are many FDA requirements pertaining to mammography. This letter pertains only to findings of our 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>.

If you have any questions about mammography facility requirements in general, please feel free to contact Murray L. Kurzman, Radiation Programs Manager, at (516) 921-2035.

Sincerely yours,


Brenda J. Holman
District Director