



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Central Region

*M3015A*

Food and Drug Administration  
Waterview Corporate Center  
10 Waterview Blvd., 3rd Floor  
Parsippany, NJ 07054

Telephone (973) 526-6007

April 4, 2000

WARNING LETTER

CERTIFIED MAIL  
RETURN RECEIPT REQUESTED

Mr. Steven Blumenfruct  
Bergen Open MRI and Diagnostics  
One West Ridgewood Avenue  
Paramus, New Jersey 07652

FILE NO.: 00-NWJ-30  
Inspection ID NO.: 2110940004

Dear Mr. Blumenfruct:

We are writing you because an inspection conducted by the State of New Jersey on behalf of the Food and Drug Administration (FDA) on March 24, 2000 revealed a serious regulatory problem involving mammography at your facility.

Under 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 Level One deficiencies:

- Phantom Quality Control (QC) records were missing for twelve weeks for Unit 1 [REDACTED] located in the Mammo Room at this site.
- Processor QC records were missing 21 out of 21 days of operation in November 1999. Processor QC records missing 100% for Processor 1 [REDACTED] located in the darkroom at this site.
- Processor QC records were missing 21 consecutive days for Processor 1 [REDACTED] located in the darkroom at this site.

The specific deficiencies noted above appeared on your MQSA Facility Inspection Report that was issued to your facility at the close of the inspection.

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Because this condition may be symptomatic of serious underlying problems that could compromise the quality of mammography at your facility, it represents a serious 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, the Mammography Quality Standards, suspension or revocation of your facility's FDA certificate, or obtaining a court injunction against further mammography.

You must act on this matter immediately. Please explain or provide to this office in writing within fifteen (15) working days from the date that you receive 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;
- equipment settings (including technique factors), raw test data, and calculated final results, where appropriate; and
- sample records that demonstrate proper record keeping procedures, if the findings relate to quality control or other records (Note: Patient names or identification should be deleted from any copies submitted).

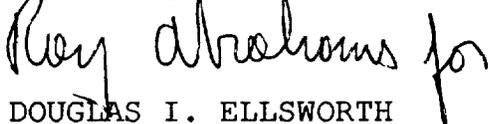
Please submit your response to Rosa L. Brown, Compliance Technician, Food and Drug Administration, New Jersey District, 10 Waterview Blvd, 3rd Floor, Parsippany, New Jersey 07054.

Finally, you should understand that there are many FDA requirements pertaining to mammography. This letter pertains only to findings disclosed during the inspection of your facility 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, MD 21045-6057 (1-800-838-7715) or through the Internet at <http://www.fda.gov>.

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If you have any specific questions about mammography facility requirements, or about the content of this letter, please feel free to contact Toniette Williams, Supervisory Investigator, at (973) 526-6018.

Sincerely,



DOUGLAS I. ELLSWORTH  
District Director  
New Jersey District Office

cc: Bureau of Radiological Health  
Department of Environmental Protection  
P.O. Box 415  
Trenton, New Jersey 08625-0415

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