DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Central Region 93170J

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

Telephone (973) 526-6007

March 25, 2002

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED
Mr. John E. Baratta
President
Diagnostic Imaging of Clifton, P.A.
1115 Clifton Avenue
Clifton, New Jersey 07013

FILE NO.: 02-NWJ-19
Inspection ID NO.: 1721550007

Dear Mr. Baratta:

A representative from the State of New Jersey under contract to the Food and Drug Administration (FDA) inspected your facility on March 8, 2002. This inspection revealed a serious regulatory problem involving mammography performed at your facility.

Under a United States Federal law, the Mammography Quality Standards Act of 1992 (MQSA) 42 U.S.C. 263b, 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 violation(s) of Section 354(f) of the Act [42 U.S.C. 263b(f)]at your facility (identified on your inspection report):

- **Processor Quality Control (QC) records for Processor #1, which document the performance of Processor QC testing, were missing for October 13, 2001; December 17, 2001; January 4, 2002; March 1-2, 2002; and March 5-7, 2002. [See 21 CFR 900.12(e)(1)].**

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

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 Standards, suspension or revocation of your facility's FDA certificate, or obtaining a court injunction against further mammography (see Sections 354(h) through (j) of the Act, 42 U.S.C. 263b(h) through (j)).

In addition, your response should address the Level 2 that were listed on the inspection report provided to you at the close of the inspection. A Level 2 finding indicates that the facility's performance is generally acceptable. However, the inspector did find one or more deviations from MQSA standards that may compromise the quality of mammography services offered by the facility. These findings are:

- **The measured darkroom fog density in your mammography darkroom was 0.14 optical density. This exceeds the allowed limit of .05 optical density. [See 21 CFR 900.12(e)(4)(i)]**

- **Processor QC records, which document the performance of processor quality control testing, were missing for two consecutive days and for three consecutive days in March 2002. (March 1-2 and March 5-7). [See 21 CFR 900.12(e)(1)]**

- **Seven mammography reports were reviewed and it was found that 4 of the 7 random reports did not contain an acceptable assessment category. [See 21 CFR 900.12(c)(1)(iv)]**

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 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;

- equipment settings (including technique factors), raw test data, and calculated final results, where appropriate; and

- sample records that demonstrate proper record keeping procedures.

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.

If you have technical questions about mammography facility requirements, or about the content of this letter, please feel free to contact Elizabeth A. Laudig at (410) 779-5441.

Sincerely,

Douglas I. Ellsworth

DOUGLAS I. ELLSWORTH
District Director
New Jersey District Office

cc: [redacted]

RLB/