DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Central Region

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

Telephone (973) 526-6007

March 19, 2003

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.: 03-NWJ-05
Inspection ID NO.: 1721550008

Dear Mr. Baratta:

On February 28, 2003, a representative from the State of New Jersey acting on behalf of the Food and Drug Administration (FDA) inspected your facility. This inspection revealed a serious problem involving the conduct of mammography at your facility. Under the Mammography Quality Standards Act of 1992 (MQSA), which is codified in Section 263b of Title 42 of the United States Code (U.S.C.), your facility must meet specific requirements to practice mammography. These requirements help protect the health of women by assuring that a facility can perform quality mammography.

The inspection revealed a violation of MQSA at your facility. This violation was noted on the MQSA Facility Inspection Report and the document *"Important Information about Your MQSA Inspection"* that the inspector left at your facility at the close of the inspection:

> **Level 2 (Repeat): One of five random reports reviewed did not contain an acceptable assessment category. [See 21 CFR 900.12(c)(1)(iv)]**

Because the continued failure to resolve this violation may be indicative of serious underlying problems that could compromise the quality of mammography at your facility, FDA may take additional actions, including but not limited to, the following:

- requiring your facility to undergo an Additional Mammography Review
- 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 MQSA standards
- seeking to suspend or revoke of your facility's FDA certificate
- seeking a court injunction against your facility

See 42 U.S.C. 263b(h)-(j) and CFR 900.12(j).

FDA may need to perform a Compliance Follow-up Inspection to determine that each problem at your facility has been corrected.

If you choose to respond to the noted violation, your response should include:

- the specific steps you have taken, or will take, to correct all of the violations noted in this letter, including projected timeframes for implementing those steps;

- the specific steps you have taken, or will take, to prevent the recurrence of similar violations, including projected timeframes for implementing those steps;

- 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/cdrh/mammography/index.html.

If you have additional or more specific 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: Judith Odonovich, MQSA Inspector
State of New Jersey
Department of Environmental Protection
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