DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Central Region 93187d

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

Telephone (973) 526-6007

April 19, 2002

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED
Lee Y. Joung, M.D.
President
Medical Park Imaging
330 Ratzer Road
Wayne, New Jersey 07470

FILE NO.: 02-NWJ-20
Inspection ID NO.: 1210000007

Dear Dr. Joung:

A representative from the State of New Jersey under contract to the Food and Drug Administration (FDA) inspected your facility on March 26, 2002. 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):

- **Your facility failed to document that phantom image quality control testing was performed. [See 21 CFR 900.12(e)(2)]. Phantom image quality control records were missing for the following weeks:**
  - **April 2-7, 2001**
  - **April 16-21,2001**
  - **May 14-19, 2001**
  - **July 23-28, 2001**
  - **August 20-25, 2001**
  - **December 10-15, 2001**
  - **January 14-19, 2002**

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, it 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)).

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/