DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
New Orleans District Office
6600 Plaza Drive, Suite 400
New Orleans, LA 70127

June 5, 2002

VIA FEDERAL EXPRESS

FACILITY ID #122945

Martin Pinstein, M.D.
Chief Radiologist
East Memphis Imaging Center, L.L.C.
6005 Park Avenue, Suite 431-B
Memphis, TN 38119

Warning Letter No. 02-NSV-25

Dear Dr. Pinstein:

Your facility was inspected on May 13, 2002 by a representative of the State of Tennessee on contract to the Food and Drug Administration (FDA). This inspection revealed a serious compromise in the quality of the mammography services offered by your facility.

Under the Mammography Quality Standards Act of 1992 (MQSA), 42 U.S.C. § 263b, and FDA's regulations at Title 21, Code of Federal Regulations (CFR) , Section 900.12, 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 recent inspection at your facility revealed the following Level 1 findings:

Level 1

The system to communicate mammography results to patients is not adequate for site East Memphis Imaging Center, L.L.C.
There is no system in place to provide timely lay summaries to patients.
There is no system in place to communicate serious or highly suggestive assessments to patients as soon as possible.

These Level 1 findings are deviations from 21 CFR § 900.12(c)(2).

The specific deficiencies noted above appeared on your MQSA Post Inspection Report which was given to your facility by the state inspector at the close of your inspection, along with instructions on how to respond to these findings. These deficiencies 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 performing further mammography.

In addition, you should also address the following deficiencies that were listed on the inspection report:

Level 2

Failed to produce documents verifying that the radiologic technologist, [redacted] met the continuing experience requirement of having performed 200 mammography examinations in the last 24 months. [See 21 CFR § 900.12(a)(2)(iv).]

4 of 5 random reports reviewed did not contain an acceptable assessment category for site East Memphis Imaging Center, L.L.C. [See 21 CFR § 900.12(c)(1)(iv).]

Medical audit and outcome analysis was not done for the facility as a whole at site East Memphis Imaging Center, L.L.C. [See 21 CFR § 900.12(f).]

Medical audit and outcome analysis was not done separately for each individual at site East Memphis Imaging Center, L.L.C. [See 21 CFR § 900.12(f)(1).]

Medical audit and outcome analysis was not performed annually at site East Memphis Imaging Center, L.L.C. [See 21 CFR § 900.12 (f)(2).]

There is no designated audit (reviewing) interpreting physician for site East Memphis Imaging Center, L.L.C. [See 21 CFR § 900.12(f)(3).]

It is your responsibility to ensure adherence to each requirement of the MQSA and FDA's regulations. You are responsible for investigating and determining the cause of these deficiencies as identified and to promptly initiate permanent corrective action.

Within 15 working days after receiving this letter, you should notify FDA in writing of each step your facility is taking to prevent the recurrence of any similar violations. Your response should include:

- The specific steps you have taken to correct the Level 1 and Level 2 violations outlined in this letter;
- Each step your facility is taking to prevent the recurrence of similar violations;
- Sample records that demonstrate proper record-keeping procedures relating to quality control or any other records that are appropriate to the noncompliance findings (NOTE: Patient names or identification should be deleted from any copies submitted).

If your facility is unable to complete these corrective actions within 15 working days, you should state the reason for the delay and the time within which the corrections will be completed.

Your reply should be directed to Joseph E. Hayes, Compliance Officer, Food and Drug Administration, 297 Plus Park Boulevard, Nashville, Tennessee 37217, telephone 615/781-5389, extension 125, with a copy to

the State of Tennessee. Should you have questions regarding the technical aspects of this letter or concerning MQSA standards, you may call Karen Smallwood, Radiation Specialist, at 615/781-5380, extension 144.

Finally, you should understand that there are many FDA requirements pertaining to mammography. This letter pertains only to findings of your 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, PO Box 6057, Columbia, MD 21045-6057 (1-800-838-7715) or through the Internet at www.fda.gov.

Sincerely,

Carl E. Draper

Carl E. Draper
Director, New Orleans District

CED:KRS:man

Cc: Darlene Nalepa-Whitmill
TN Dept. Of Environment and Conservation
2700 Middlebrook Pike, Suite 220
Knoxville, TN 37921

Jessica Soileau
Division of Radiological Health
2510 Mt. Moriah Rd., Suite E-645
Perimeter Park
Memphis, TN 38115

Priscilla F. Butler, MS
Director, Breast Imaging Accreditation Programs
Standards and Accreditation Department
American College of Radiology
1891 Preston White Drive
Reston, VA 22091

Director, Government Relations
C/o American College of Radiology
1891 Preston White Drive
Reston, VA 22091