DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

93534d

Food and Drug Administration
555 Winderley Pl., Ste. 200
Maitland, Fl 32751

VIA FEDERAL EXPRESS

WARNING LETTER

FLA-02-61

September 12, 2002

FACILITY ID # 1184176

Michael Levine, M.D., Medical Director
All Florida Diagnostic Center
1487 South Highway 301
Sumterville, Florida 33585

Dear Dr. Levine:

We are writing to you because on July 17, 2002, a representative of the State of Florida, acting on behalf of the Food and Drug Administration (FDA) inspected your facility. This inspection revealed serious regulatory problems involving the mammography at your facility.

Under United States Federal law, the Mammography Quality Standards Act of 1992, 42 U.S.C. § 263b, your facility must meet specific requirements for mammography. These requirements help protect the health of women by ensuring that a facility can perform quality mammography. The inspection revealed the following REPEAT violations at your facility.

Your facility failed to prepare a written report of the results of each mammography examination performed under its certificate. FDA regulations require the mammography report to include the overall final assessment of findings, classified by category as required by 21 CFR § 900.12(c) (1) (iv). For example, a repeat violation was identified during the previous inspection of your facility dated July 23, 2001, for failure to prepare a written report that includes an overall final assessment of the findings.

Important Note Regarding Repeat Findings: An observation marked with (REPEAT) indicates that the finding or violation was cited during the previous inspection and is, therefore, a repeat finding. A finding is considered a repeat finding if the same type of violation was cited during the previous inspection, whether or not the finding is associated with the same piece of equipment (x-ray unit, processor, or darkroom) or the same personnel in a given category.

The specific problems noted above appeared on the MQSA Facility Inspection Report that was issued to your facility at the close of the inspection on July 17, 2002.

Because these conditions may be symptomatic of serious underlying problems that could compromise the quality of mammography at your facility, they represent 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 $10,000.00 for each failure, or each day of failure to substantially comply with the requirements of the Mammography Standards Act, suspending or revoking your facility's FDA certificate, or obtaining a court injunction against conducting further mammography examinations.

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 receive this letter:

- the specific steps you have taken to correct all of the violations noted in this letter;
- each step your facility is taking to prevent the recurrence of similar violations; and
- sample records that demonstrate proper record keeping procedures (Note: Patient names or identification should be deleted from any copies submitted).

Please submit your response to Timothy J. Couzins, Compliance Officer, Food and Drug Administration, 555 Winderley Place, Suite 200, Maitland, Florida 32751,telephone number (407) 475-4728.

Finally, you should understand that there are many FDA requirements pertaining to mammography. This letter pertains only to findings observations made during 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, P. O. Box 6057, Columbia, Maryland 21045-6057, telephone number (1-800-838-7715) or through the Internet at http://www.fda.gov.

If you have more specific questions about FDA's mammography facility requirements, or about the content of this letter, please contact D. Janneth Caycedo, Boca Resident Post, Food and Drug Administration, Interstate Plaza, 1499 W. Palmetto Park Rd., Suite 110, Boca Raton, Florida 33486, telephone number (561) 338-5236, ext. 23.

Sincerely,

Emma R. Singleton
Director, Florida District