HFI-35

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

93-29d

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

CERTIFIED MAIL
RETURNED RECEIPT REQUESTED

WARNING LETTER

FLA-03-11

December 3, 2002

FACILITY ID # 123307

Nicolau Sacaquini, Administrator
Medical Diagnostic Center (Southside)
3550 University Boulevard, South Suite 102
Jacksonville, Florida 32216

Dear Mr. Sacaquini:

We are writing you because a representative of the State of Florida acting on behalf of the Food and Drug Administration (FDA) inspected your facility on October 29, 2002. This inspection revealed serious compromise in the quality of the mammography services offered by your facility.

Under the Mammography Quality Standards Act of 1992, 42 § 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 recent inspection at your facility revealed the following Level 1 finding:

> Each facility shall send each patient a summary of the mammography report written in lay terms within 30 days of the mammographic examination. If assessments are ``Suspicious" or ``Highly suggestive of malignancy," the facility shall make reasonable attempts to ensure that the results are communicated to the patient as soon as possible as required by 21 § 900.12(c)(2). Your facility does not have a system to timely communicate results to your patients e.g., Dr. Wiedenmann stated that your facility does not provide written reports to patients that were notified verbally.

The specific problem noted above appeared on your MQSA Facility Inspection Report, which was issued to your facility at the close of the inspection. Since 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, seeking civil money penalties, suspension or revocation of your facility's FDA certificate, or seeking court injunction against further mammography.

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:

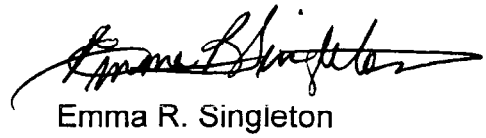
- the specific steps you have taken to correct all of the violations noted in this letter;
- each step your facility is taking to prevent the recurrence of similar violations; and
- sample records that demonstrate proper record keeping procedures, if the findings relate to quality control or other records (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.

There are many FDA requirements pertaining to mammography. This letter concerns only the findings of your recent 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 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 Road, Suite 110, Boca Raton, Florida 33486, telephone number (561) 338-5236, ext. 23.

Sincerely,



Emma R. Singleton
Director, Florida District