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VIA FEDERAL EXPRESS

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

WARNING LETTER

FLA-01-11

November 8, 2000

FACILITY ID # 223322

Luis Sanchez, Owner  
Spectrum Medical Services, Inc  
7171 Coral Way Suite 100  
Miami, Florida 33155

Dear Mr. Sanchez:

We are writing to you because on October 26, 2000, your facility was inspected by a representative of the State of FL, acting in behalf of the Food and Drug Administration (FDA). This inspection revealed a serious regulatory problem involving the mammography at your facility. Under a United States Federal law, the Mammography Quality Standards Act of 1992, 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 level 1 and level 2 findings at your facility:

Level 1: Processor quality control records were missing for eight consecutive days during September 2000 for Kodak O-Mat processor.

Level 2: There is no written procedure for handling consumer complaints. There is no written procedure for infection control.

Phantom QC records were missing for at least two weeks for the General Electric unit.

Radiology technologists, [REDACTED], did not meet the education requirement of having completed a minimum of 15 CEUs in mammography in a 36-month period.

There was no designated audit (reviewing) interpreting physician for the facility.

There were no attempts to obtain patient biopsy results.

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

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 all of 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, 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, U.S. Food & Drug Administration, 555 Winderley Place, Suite 200, Maitland, Florida 32751, (407) 475-4728.

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, P.O. Box 6057, Columbia, MD 21045-6057 (1-800-838-7715) or through the Internet at <http://www.fda.gov>.

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If you have more specific questions about mammography facility requirements, or about the content of this letter, please feel free to contact D. Janneth Caycedo (Boca Resident Post, FDA) at 561-338-5236 ext 23.

Sincerely,

A handwritten signature in cursive script that reads "Emma R. Singleton".

Emma R. Singleton  
Director, Florida District