DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration
Florida District
555 Winderley Place, Suite 200
Maitland, Florida 32751

Telephone: 407-475-4700
FAX: 407-475-4769

93438d

VIA FEDERAL EXPRESS

WARNING LETTER

FLA-02-55

July 31, 2002

FACILITY ID # 161470 & 214965

Mr. Peter Aguirre
Administrative Director, Imaging Services
Osceola Regional Medical Center
700 West Oak Street
P.O. Box 422589
Kissimmee, FL 34741, and

Osceola Imaging Center
3501 W Vine Street, Suite 126
Kissimmee, FL 34741

Dear Mr. Aguirre:

We are writing to you because on June 18, 2002, a representative from the State of Florida, acting on behalf of the Food and Drug Administration (FDA), inspected both of the above referenced facilities. These inspections revealed serious regulatory problems involving the mammography at these facilities.

Under United States Federal law, the Mammography Quality Standards Act of 1992, 42 USC § 263b, your facilities must meet specific requirements for mammography. These requirements help protect the health of women by assuring that a facility can perform quality mammography. The inspections revealed the following violations at your facilities:

Both facilities failed to produce documents verifying that interpreting physician(s) met the initial requirements of being certified in the appropriate specialty by an FDA approved board or that they have 2 (interim) or 3 (final) months of initial training; failed to produce documents showing that the physician(s) meet the initial requirement of having interpreted or multi-read 240 mammograms in 6 months, and failed to produce documents showing that the physician(s) meet the initial requirement of having 40 (interim) or 60 (final) hours of category I medical education in mammography as required by 21 CFR 900.12(a)(1)(i), (B)(1)&(2), (C), and (D). For example, your facilities failed to produce documentation verifying that both Drs. [redacted] and [redacted] met their initial qualification requirements.

The specific problems noted above appeared on your MQSA Facility Inspection Reports, which were issued to your facilities at the close of the inspection. These conditions may be symptomatic of serious underlying problems that could compromise the quality of mammography at your facilities, and they represent serious violations of the law that may result in FDA taking regulatory action. Possible actions include, but are not limited to, placing your facilities under a Directed Plan of Correction, charging your facilities for the cost of on-site monitoring, assessing civil money penalties up to $10,000.00 for each failure to substantially comply with, or each day of failure to substantially comply with, the Standards, suspension or revocation of your facilities' 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 receive this letter:

- the specific steps you have taken to correct all of the violations noted in this letter;
- each step your facilities are 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, 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 of your inspections 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 Rd., Ste. 110, Boca Raton, Florida 33486, telephone number (561) 338-5236, Ext. 23.

Sincerely,

Emma R. Singleton
Director, Florida District