DEPARTMENT OF HEALTH & HUMAN SERVICES

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

VIA FEDERAL EXPRESS

WARNING LETTER

FLA-02-51

June 28, 2002

FACILITY ID # 192328

David Black, Administrator
Comprehensive Breast Care Center
1380 N.E. Miami Gardens Drive Suite 105
North Miami Beach, Florida 33179

Dear Mr. Black:

We are writing to you because on May 2, 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 USC § 263b, your facility must meet specific requirements for mammography (the "Standards"). These requirements help protect the health of women by assuring that a facility can perform quality mammography.

The inspection revealed that your facility failed to collect and review outcome data for all mammograms performed, including follow-up on the disposition of all positive mammograms and correlation of pathology results with the interpreting physician's mammography report, for all interpreting physicians at the facility, both individually and collectively, as required by 21 CFR § 900.12(f)(1). That analysis must be performed at least once every year. 21 CFR § 900.12(f)(2).

Each facility must designate at least one interpreting physician to perform that annual review of the medical outcomes audit data. This individual shall record the dates of the audit period(s) and shall be responsible for analyzing results based on the audit. That individual shall also be responsible for documenting the results and for notifying the other interpreting physicians at the facility of their results and the facility aggregate results. 21 CFR § 900.12(f)(3).

The noncompliance's referenced above – failure to perform outcome analysis annually, failure to perform outcome analysis for each interpreting physician individually, and failure to perform outcome analysis for all interpreting physicians collectively -- are REPEAT violations from the previous inspection of your facility, as noted on the MQSA Facility Inspection Report, which was issued to your facility at the close of the inspection. 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.

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 and charging your facility for the cost of on-site monitoring. Continuing failure to correct these violations could also cause FDA to seek 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 facility's FDA certificate; and/or a court injunction against further mammography.

In addition, the inspection also revealed the following violations of the Standard:

- Your facility failed to perform Quality Control tests at the most commonly used clinical setting for kVp on phantoms for unit 1 (Fisher Imaging Corp., ATH, room Mammo) and unit 2 (General Electric Co., DMR, room Mammo), as required by 21 CFR § 900.12(e)(5)(ii)(2).

- In some instances when patients had mammograms done at your facility but biopsies done at other facilities, your facility failed to obtain the biopsy results from those other facilities, and has no evidence that it attempted to obtain those biopsy results. Thus, the facility was not able to correlate pathology results of those mammograms with the mammography reports, and apparently did not even attempt to follow up on the disposition of those mammograms. See 21 CFR § 900.12(f)(1).

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;

- 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, Ste. 200, Maitland, Florida 32751, telephone no. (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, Maryland 21045-6057, telephone no. (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 no. (561) 338-5236, ext. 23.

Sincerely,

Emma R. Singleton
Director, Florida District