DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

VIA FEDERAL EXPRESS

WARNING LETTER

FLA-02-49

June 10, 2002

FACILITY ID # 224459

Kim Melendez, Chief Technologist
Bonita Community Health Center
3501 Health Center Boulevard
Bonita Springs, Florida 34135

Dear Ms. Melendez:

On May 2, 2002 a representative from 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. These requirements help protect the health of women by assuring that a facility can perform quality mammography. The inspection revealed the following violations at your facility.

Your facility failed to perform film processor performance testing each day that clinical films are processed, and before any clinical films are processed that day as required by 21 CFR 900.12(e)(1)(i), (ii), (iii). For example, daily quality control tests shall include an assessment of base plus fog density within + 0.03 of the established operating level (900.12(e)(1)(i)); an assessment of the mid-density shall be within +/-0.15 of the established operating level (900.12(e)(1)(ii)); and an assessment of the density difference shall be within +/-0.15 of the established operating level (900.12(e)(1)(iii)). Mammograms were processed from February 5 to February 14, 2002, in the Kodak Mammo processor when the processor was out of limits.

Your firm failed to ensure that records concerning corrective actions for processor QC failures are properly maintained and updated as required by 21 CFR 900.12(d)(2). For example, documentation was not maintained for corrective actions taken for the Kodak processor QC failures in the Mammo room.

Your facility failed to establish a system 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 as required by 21 CFR 900.12(f)(1). For example, analyses of these outcome data were not made individually and/or collectively for all interpreting physicians at your facility.

Your facility failed to perform first audit analysis no later than 12 months after the date your facility became certified, or 12 months after April 28, 1999, whichever date is later as required by 21 CFR 900.12(f)(2). For example, medical audits and outcome analysis were not done for your facility: as a whole; for each individual radiologist; and at the required frequency. Additionally, the audit analysis shall be completed within the next 12 months to permit completion of diagnostic procedures and data collection. Subsequent audit analyses will be conducted at least once every 12 months.

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 serious violation(s) 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 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 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;
- 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, 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