DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

939554

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

VIA CERTIFIED MAIL

WARNING LETTER

FLA-03-27

March 27, 2003

FACILITY ID # 1458540009

Richard Gould
Director of Radiology
Watson Clinic LLP
1600 Lakeland Hills Boulevard
P.O. Box 95000
Lakeland, Florida 33805

Dear Mr. Gould:

We are writing to you because on February 13, 2003, a representative of the State of Florida, acting on behalf of the Food and Drug Administration (FDA), inspected your facility. This inspection revealed serious problems involving the mammography at your facility.

Under United States Federal law, the Mammography Quality Standards Act of 1992 (MQSA), 42 U.S.C. § 263b, your facility must meet specific requirements for mammography. These requirements help protect the health of women by ensuring that a facility can perform quality mammography. The inspection revealed the following REPEAT violation at your facility.

Level 2 (Repeat): Your facility failed to produce documents verifying that the interpreting physician taught or completed at least 15 category I continuing medical education units (CME) in mammography during the 36 months immediately preceding the date of the facility's annual MQSA inspection or the last day of the calendar quarter preceding the inspection or any date in between the two as required by 21 CFR 900.12(a)(1)(ii)(B). Specifically, there were no documents verifying that interpreting physician, [redacted] met the continuing education requirement or completed 15 CMEs in 36 months. This is a repeat violation identified during the previous inspection of your facility dated February 14, 2002.

Important Note Regarding Repeat Findings: An observation marked with (REPEAT) indicates that the finding or violation was cited during the previous 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.

The specific problem noted above appeared on the MQSA Facility Inspection Report that was issued to your facility at the close of the inspection on February 13, 2003.

Because continued failure to resolve this violation may be indicative of serious underlying problems that could compromise the quality of mammography at your facility, FDA may take additional actions, including, but not limited to: requiring your facility to undergo Additional Mammography Review, placing your facility under a Directed Plan of Correction, charging your facility for the cost of on-site monitoring, seeking civil money penalties up to $10,000.00 for each failure, or each day of failure to substantially comply with the requirements of the MQSA, seeking to suspend or revoke your facility's FDA certificate, or seeking a court injunction against your facility. See 42 U.S.C. 263b(h)-(j) and 21 CFR 900.12(j).

Please respond to this office in writing within fifteen (15) working days from the date you receive this letter. FDA may need to perform a Compliance Follow-up Inspection to determine that each problem at your facility has been corrected. Your response should include:

- the specific steps you have taken, or will take, to correct all of the violations noted in this letter, including projected timeframes for implementing those steps;
- the specific steps you have taken, or will take to prevent the recurrence of similar violations, including projected timeframes for implementing those steps; and
- sample records that demonstrate proper record keeping procedures (Note: Patient names or other information that would likely reveal the patient's identity 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 observations made during 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 number (1-800-838-7715) or through the Internet at http://www.fda.gov/cdrh/mammography/index.html.

If you have more specific questions about FDA's 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., Suite 110, Boca Raton, Florida 33486, telephone number (561) 338-5236, ext. 23.

Sincerely,

for Emma R. Singleton
Director, Florida District