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Food and Drug Administration
Minneapolis District
240 Hennepin Avenue
Minneapolis MN 55401-1999
Telephone: 612-334-4100

February 11, 2000

xc: HFI-35
DWA

WARNING LETTER

**CERTIFIED MAIL
RETURN RECEIPT REQUESTED**

Refer to MIN 00 - 18

Lynn Diulio, M.D.
Chief Executive Officer
Women Care
20611 Watertown Road
Waukesha, Wisconsin 53186

Dear Dr. Diulio:

On February 1, 2000, a representative of the State of Wisconsin, acting on behalf of the Food and Drug Administration (FDA), inspected your facility (inspection ID 1659020008). 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 (MQSA), 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. Based on the documentation your site presented at the time of the inspection, the following Level 1 and Level 2 findings were documented at your facility:

Level 1 Non-Compliance:

1. The system to communicate results is inadequate for the Women Care site because there is no system in place to provide timely lay summaries. For patients whose mammogram bear the assessment category "Incomplete = Needs Additional Imaging Evaluation," the lay summary is not being sent out until the patient receives additional clinical work-up. Examples were noted that this policy has led to your site not meeting the regulatory timeframe of 30 days to issue the lay letter.

Level 2 Non-Compliances:

2. There is no written procedure for handling consumer mammography complaints at Women Care in accordance with Title 21, Code of Federal Regulations, Part 900.12(h)(1)(2)(3)(4).

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3. On three days during the past year your site processed mammograms through a film processor  when the quality control limits were exceeded. Federal regulation requires that no mammography (clinical) films be processed through an out-of-control film processor.

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

Note: As with past MQSA inspections conducted at your site, portions of the required personnel qualification documents were unavailable during the inspection. MQSA inspections are pre-announced; this provides you time to consolidate the required documentation. For future inspections please ensure that complete personnel qualifications of all personnel that have performed mammography for your site in the proceeding year be available to the inspector on the day 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 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.

Please submit your response to Thomas W. Garvin, Radiological Health Specialist, FDA, 2675 N. Mayfair Road, Suite 200, Milwaukee, WI 53226-1305.

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

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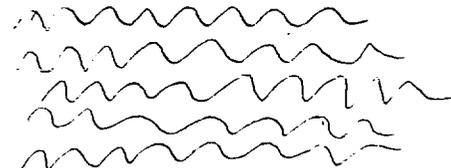
Administration, P.O. Box 6057, Columbia, MD 21045-6057 (1-800-838-7715) or
through the Internet at <http://www.fda.gov/cdrh/mammography/index.html>.

If you have specific questions about mammography facility requirements or about
the content of this letter please feel free to phone Mr. Garvin at (414) 771-7167 ext.
12.

Sincerely,


James A. Rahto
Director
Minneapolis District

TWG/ccl

xc: 

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