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**PURGED** *EAK*

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

April 28, 2000

xc: HFI-35  
DWA

**WARNING LETTER**

**CERTIFIED MAIL**  
**RETURN RECEIPT REQUESTED**

Refer to MIN 00 - 31

Eugene W. Monroe, M.D.  
President  
Advanced Health Care  
P.O. Box 099  
Milwaukee, Wisconsin 53209-0996

Dear Dr. Monroe:

On April 19, 2000, a representative of the State of Wisconsin, acting on behalf of the Food and Drug Administration (FDA), inspected your West Bend Clinic/Advanced Health Care facility at 1700 W. Paradise Drive, West Bend, WI, 53095 (inspection ID 1461590008). 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-Compliances**

1. Phantom QC records were missing for five weeks for Unit 1  
( mammography room #2).
2. Phantom QC records were missing for six weeks for Unit 2  
( mammography room #1).

**Level 2 Non-Compliances**

3. The mammography equipment evaluation by a medical physicist for Unit 2  
( mammography room 1 or related

Page Two

Eugene W. Monroe, M.D.  
April 28, 2000

processor) was not done. Note: FDA acknowledges that this was corrected during the inspection.

4. Five of 5 randomly selected mammography reports reviewed did not contain an assessment category for site: West Bend Clinic/Advanced Health Care. See Title 21, Code of Federal Regulations, Part 900.12(c)(1)(i), (ii), (iii)(A)(B)(C)(D)(E), (iv), (v), and (vi) for requirement.

The specific problems noted above appeared on your MQSA Facility Inspection Report which was issued to your facility following 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 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, Food and Drug Administration, 2675 N. Mayfair Road, Suite 200, Milwaukee, WI, 53226-1305.

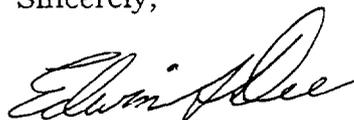
Finally, you should understand that there are many FDA requirements pertaining to mammography. This letter pertains only to findings of your inspection and does not necessarily address other obligations you have under the law. You may obtain general information about all of FDA's requirements for mammography facilities by contacting the Mammography Quality Assurance Program, Food and Drug 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>.

Page Three

Eugene W. Monroe  
April 28, 2000

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

Sincerely,



Edwin S. Dee  
Acting Director  
Minneapolis District

TWG/ccl

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