DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
New Orleans District Office
6600 Plaza Drive, Suite 400
New Orleans, LA 70127 NEW

January 10, 2003

VIA FEDERAL EXPRESS

FACILITY ID #108753

Philip Parker, Administrator
D.W. McMillan Hospital
1301 Belleville Avenue
Brewton, AL 36426

Warning Letter No. 03-NSV-06

Dear Mr. Parker:

Your facility was inspected on December 13, 2002 by a representative of the State of Alabama acting on behalf of the Food and Drug Administration (FDA). This inspection revealed a serious regulatory problem involving the mammography services offered by your facility.

Under the Mammography Quality Standards Act of 1992 (MQSA), 42 U.S.C. § 236b, 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 recent inspection at your facility revealed the following Level 1 finding:

Level 1

The system to communicate results is not adequate for site D.W. McMillan Hospital because:

- There is no system in place to provide timely lay summaries of mammography results to patients – *21 C.F.R. § 900.12(c)(2)*

This specific deficiency noted above appeared on your MQSA Post Inspection Report which was sent to your facility by the state inspector along with instructions on how to respond to this finding. A Level 1 finding indicates that the inspector found one or more deviations from MQSA standards that may seriously compromise the quality of mammography services offered by the facility.

In addition, you should also address the following deficiency that was also listed on the inspection report:

Level 2

The mammography processor equipment evaluation by a medical physicist for processor 1, [redacted] or [redacted]. Mammo room, site D.W. McMillan Hospital was not done – *21 C.F.R. § 900.12(e)(10)*

Because these conditions may be symptomatic of serious underlying problems that could compromise the quality of mammography at your facility, they represent a 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 Direct Plan of Correction, charging your facility for the cost of on-site monitoring, seeking civil money penalties up to $10,000 for each failure to substantially comply, or each day of failure to comply with, MQSA standards, seeking suspension or revocation of your facility's FDA certificate, or seeking a court injunction against further mammography. See 42 U.S.C. § 236b(h)-(j).

It is your responsibility to ensure adherence to each requirement of the MQSA and FDA regulations. You are responsible for investigating and determining the cause of these deficiencies as identified and for promptly initiating permanent corrective actions.

Within 15 working days after receiving this letter, you should notify FDA in writing of each step your facility is taking to prevent the recurrence of any similar violations. Your response should include:

- The specific steps you have taken to correct the Level 1 and Level 2 violations as outlined in this letter;
- Each step your facility is taking to prevent the recurrence of similar violations;
- Sample records that demonstrate proper record-keeping procedures relating to quality control or any other records that relate to the violations (NOTE: Patient names or identification should be deleted from any copies submitted).

If your facility is unable to complete these corrective actions within 15 working days, you should state the reason for the delay and the time within which the corrections will be completed.

Your reply should be directed to Joseph E. Hayes, Compliance Officer, Food and Drug Administration, 297 Plus Park Boulevard, Nashville, Tennessee 37217, telephone 615/781-5389, extension 125, with a copy to the State of Alabama.

Finally, you should understand that there are many FDA requirements pertaining to mammography. This letter pertains only to certain findings of your inspection and does not necessarily address other obligations you have under the law. You may obtain general information about all 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.

Should you have any questions regarding the technical aspects of this letter or concerning MQSA standards, you may call Karen Smallwood, Radiation Specialist, at 615/781-5380, extension 144.

Sincerely,

Patricia K. Schafer

Patricia K. Schafer
Acting Director, New Orleans District