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DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration
Baltimore District Office
6000 Metro Drive
Suite 101
Baltimore, MD 21215-3215
Telephone: (410) 779-5454

04-BLT-07

WARNING LETTER

November 24, 2003

Certified Mail
Return Receipt Requested

Ms. Janice M. Diserio, Director of Medical Imaging
Weirton Medical Center
601 South Colliers Way
Weirton, West Virginia 26062

Dear Ms. Diserio:

On September 24, 2003, a representative of the State of West Virginia, acting on behalf of the Food and Drug Administration (FDA), inspected your facility. This inspection revealed a serious problem involving the conduct of mammography at your facility. Under the Mammography Quality Standards Act of 1992 ("MQSA") which is codified in Section 263b of Title 42 of the United States Code (USC), your facility must meet specific requirements to practice mammography. These requirements help protect the health of women by assuring that a facility can perform quality mammography.

The inspection revealed violations of the MQSA at your facility. These violations were noted on the MQSA Facility Inspection Report and the document *"Important Information about Your MQSA Inspection"* that the inspector left with your facility at the close of the inspection. The violations are again identified below.

Level 2 Repeat: Your facility failed to produce documents verifying that [redacted] met the continuing education requirement of having taught or completed at least 15 units in mammography in the 36 months prior to the date of your inspection. [21 CFR 900.12(a)(2)(iii)(A)]

Level 2 Repeat: Your facility failed to produce documents verifying that [redacted] met the continuing education requirement of having taught or completed at least 15 units in mammography in the 36 months prior to the date of your inspection. [21 CFR 900.12(a)(2)(iii)(A)]

Because the failure to resolve these violations 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, the following:

- requiring your facility to undergo an 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 for each failure to substantially comply with, or each day of failure to substantially comply with, MQSA standards
- seeking to suspend or revoke your facility's FDA certificate

See 42 USC 263b(h)-(j) and 21 CFR 900.12(j).

FDA may need to perform a Compliance Follow-up Inspection to determine that each problem at your facility has been corrected.

You should respond in writing to FDA within fifteen (15) working days from the date you received this letter. Your response should address the findings listed above and include:

1. 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;

2. the specific steps you have taken, or will take, to prevent the recurrence of similar violations, including projected timeframes for implementing those steps;

3. sample records that demonstrate proper record keeping procedures;

Your response should be submitted to: Food and Drug Administration, 6000 Metro Drive, Suite 101, Baltimore, Maryland 21215, to the attention of Elizabeth A. Laudig, Compliance Officer.

Please send a copy of your response to:

Jamie Browning
Office of Environmental Health Services
Radiological Health Program
815 Quarrier Street, Suite 418
Charleston, West Virginia 25301

Finally, you should understand that there are many requirements pertaining to mammography. This letter pertains only to violations related to the recent inspection of your facility 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.

If you have additional or more specific questions about mammography facility requirements, or about the content of this letter, please feel free to contact Elizabeth A. Laudig at (410) 779-5441.

Sincerely yours,

Lee Bowers
Director, Baltimore District

cc: Jamie Browning
Office of Environmental Health Services
Radiological Health Program
815 Quarrier Street, Suite 418
Charleston, West Virginia 25301

Priscilla F. Butler, M.S.
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