



DEPARTMENT OF HEALTH AND HUMAN SERVICES

941700

Food and Drug Administration
New Orleans District Office
Nashville Branch Office
297 Plus Park Blvd.
Nashville, TN 37217

Telephone: 615-781-5380
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July 31, 2003

VIA FEDERAL EXPRESS
OVERNIGHT DELIVERY

FACILITY ID #217950

Catherine Gleason, M.D.
The Breast Center
1121 Mimosa Drive
Oxford, MS 38655

Warning Letter No. 03-NSV-22

Dear Dr. Gleason:

An inspection of your facility was conducted on July 10, 2003 by a representative of the State of Mississippi acting on behalf of the Food and Drug Administration (FDA). This inspection revealed a serious compromise in the quality of the mammography services offered by this 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 inspection revealed the following violations of the MQSA at your facility:

Level 1: Your facility failed to produce documents verifying that the interpreting physician, [REDACTED] met the initial requirement of being certified in the appropriate specialty by an FDA-approved board or having 3 months of initial training in the interpretation of mammograms. [See 21 CFR 900.12(a)(1)(i)(B) and 900.12(a)(4).]

Level 2: Processor quality control records for February 2003 were missing for at least 10 percent but less than 30 percent of operating days for processor 1, [REDACTED] or [REDACTED] Darkroom, at site The Breast Center. [See 21 CFR 900.12(d)(2) and 900.12(e)(2)(i)-(iii).]

Level 2: Your facility failed to produce documents verifying that the interpreting physician, [REDACTED], met the initial experience requirement of having interpreted or multi-read 240 mammograms in 6 months. [21 CFR 900.12(a)(1)(i)(D) and 900.12(a)(4).]

Level 2: Your facility failed to produce documents verifying that the interpreting physician, [REDACTED] met the initial requirement of having 60 hours of category I medical education in mammography. [21 CFR 900.12(a)(1)(i)(C) and 900.12(a)(4).]

Level 2: In 4 of the 5 written mammography reports reviewed during the inspection, your facility failed to include the name of the interpreting physician who interpreted the mammogram. [21 CFR 900.12(c)(1)(iii).]

A continued failure to resolve these violations could be indicative of serious underlying problems that could compromise the quality of mammography at your facility. Consequently, if these violations are not resolved, 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

FDA may also take the following actions with respect to unresolved MQSA violations, depending on the circumstances:

- Requiring a facility to notify patients who received mammograms at your facility, and their referring physicians, of the deficiencies, the potential harm resulting from such deficiencies, appropriate remedial measures, and other relevant information
- Seeking a court injunction against a facility

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.

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 similar violations. Your response should 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 of steps you have taken, or will take, to prevent the recurrence of similar violations, including projected timeframes for implementing those steps; and
3. Sample records that demonstrate proper record keeping procedures.

Please submit your response to this letter to:

Joseph E. Hayes
Compliance Officer
Food and Drug Administration
297 Plus Park Boulevard
Nashville, TN 37127

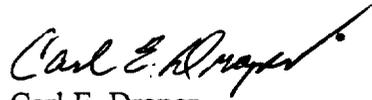
Please send a copy of your response to:

Jimmy D. Tallman
State of Mississippi
X-Ray Branch
3150 Lawson Street
P.O. Box 1700
Jackson, MS 39215-1700

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 Karen Smallwood, Radiation Specialist, at 615-781-5380, extension 144.

Sincerely,


Carl E. Draper
Director, New Orleans District

CED:krs

cc: Jimmy D. Tallman
State of Mississippi
X-Ray Branch
3150 Lawson Street
P.O. Box 1700
Jackson, MS 39215-1700

Priscilla F. Butler, MS
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