DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Atlanta District Office
60 Eighth Street N.E.
Atlanta, GA 30309

Telephone: 404-253-1161
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93415d

March 13, 2003

VIA FEDERAL EXPRESS

Janice Benoit, Chief Technologist
Healthsouth Diagnostic Center of Fayetteville
3186 Village Drive
Suite 101
Fayetteville, NC 28304

Inspection ID # 1126560008

WARNING LETTER
(03-ATL-14)

Dear Ms. Benoit:

Your facility was inspected on February 20, 2003, by a representative of the North Carolina Department of Environment and Natural Resources (DENR), Division of Radiation Protection, acting on behalf of the United States Food and Drug Administration (FDA). This inspection revealed a serious compromise in the quality of the mammography services offered by your facility.

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

Level 1 Noncompliance:

- Mammograms were processed in processor # 2 [redacted] located in the mammography room, when it was out of limits on at least 5 days. [21 C.F.R. § 900.12(e)(8)(ii)(A); 21 C.F.R. §§ 900.12(e)(1)-(5) specify the quality control limits]

- The system to communicate results is not adequate because there is no system in place to provide timely lay summaries to each patient. The lay letter is not sent to patients with an "incomplete" exam. [21 C.F.R. § 900.12(c)(2)]

Level 2 Noncompliance:

- Corrective actions for processor QC failures were not documented at least once for processor #2 described above. [21 C.F.R. § 900.12(e)(8)(ii)]

- Corrective action before further exams, for a failing image score, or a phantom background optical density, or density difference outside the allowable regulatory limits, was not documented for unit # 4, [redacted], located in Room #1. [21 C.F.R. §900.12(e)(8)(ii)]

The specific problems noted above appeared on your MQSA Facility Inspection Report, which was issued to your facility at the close of the inspection. These conditions represent a violation of the law, which may result in FDA taking additional action including, but not limited to: 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, seeking to suspend or revoke your facility's FDA certificate, or seeking 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 fifteen (15) working days after receiving this letter:

- The specific steps you have taken, or will take, to correct the violations noted in this letter;
- Each step your facility is taking, or will take, to prevent the recurrence of similar violations; and
- Sample records that demonstrate proper recordkeeping. **(Note: Patient names or identification should be deleted from any copies submitted.)**

If your facility is unable to complete the corrective action within 15 working days, you should state the reason for the delay and time within which corrections will be completed. Please send the original copy of your response to: Serene A. Kimel, Compliance Officer, U.S. Food and Drug Administration, 60 8th St., NE Atlanta, GA 30309. You should also send a copy of your response to the North Carolina DENR, Division of Radiation Protection, 3825 Barrett Drive, Raleigh, NC 27609-7221 and to Thomas Clarida, U.S. Food and Drug Administration, 5701 Executive Center Drive, Suite 104, Charlotte, NC 28212.

Finally, you should understand that there are many FDA requirements pertaining to mammography. This letter concerns only the findings of your recent 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.

If you have any questions regarding this letter or how to ensure you are meeting MQSA standards, please call Thomas Clarida at 704-344-6116.

Sincerely yours,

Mary Woleske

Mary H. Woleske, Director
Atlanta District