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Food and Drug Administration
Atlanta District Office

DEPARTMENT OF HEALTH AND HUMAN SERVICES

60 Eighth Street, N.E.
Atlanta, Georgia 30309

October 8, 2002

VIA FEDERAL EXPRESS

Jean Griswold, Founder & CEO
Mobile Health Outreach
724-C North I-85 Service Road
Charlotte, NC 28216

Inspection ID: 2214630004

WARNING LETTER
(03-ATL-01)

Dear Ms. Griswold:

Your facility was inspected on September 19, 2002 by a representative of the North Carolina Department of Environment & Natural Resources (DENR), Division of Radiation Protection, acting on behalf of the Food and Drug Administration (FDA). This inspection revealed a serious regulatory problem involving the mammography services at 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 and Level 2 findings:

Level 1 Noncompliance:

- Phantom QC records were missing for at least 4 weeks for unit #1, [redacted] This is a violation of 21 CFR § 900.12 (e)(2).

Level 2 Noncompliance:

- Corrective actions for processor QC failures were not documented at least once for processor #1, [redacted]. This is a violation of 21 CFR §900.12 (e)(8).

- Mammograms were processed in processor #1, described above, when it was out of limits on at least 2 but less than 5 days. This is a violation of 21 CFR § 900.12(e)(8).

- Processor QC records in the month of 03/2002 were missing for a least 10% but less than 30% of operating days, for processor #1 described above. This is a violation of 21 CFR § 900.12(e)(1).

- A performance verification test was not conducted after each move for mobile unit #1[redacted] This is a violation of 21 CFR § 900.12(e)(7).

- 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 #1, described above. This is a violation of 21 CFR § 900.12(e)(8).

The specific problems noted above appeared on your MQSA Facility Inspection Report, which was issued to your facility at 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. FDA may take additional actions, including, but not limited to, placing your facility under a Directed Plan of Correction (DPC), 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 mammography standards, or suspending or revoking your facility's FDA certificate.

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 to correct the violation 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 recordkeeping procedures, if the findings relate to quality control or other records. **(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 the 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 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 pertains only to findings related to the 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 feel free to contact Thomas Clarida at 704-344-6116.

Sincerely yours,

Barbara A. Wood, Acting Director
Atlanta District

Cc: [redacted]