



Refer to: CFN 1123966
Facility ID: 104190

Food and Drug Admin.
Baltimore District Office
Central Region
900 Madison Avenue
Baltimore, Maryland 21201
Telephone: (410) 962-3591
FAX: (410) 962-3321

mzh/adin

February 4, 2000

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Wilbur J. Baggs, President
Breast Diagnostic Center
316 Main Street
Suite A
Newport News, Virginia 23601

Re: Inspection ID#1041900005

Dear Mr. Baggs:

Your facility was inspected on January 21, 2000 by a representative from the Commonwealth of Virginia under contract to the Food and Drug Administration (FDA). This inspection revealed a serious regulatory problem involving mammography performed at your facility.

Under a United States Federal law, the Mammography Quality Standards Act (MQSA) of 1992, your facility must meet specific requirements for mammography. These requirements help protect the public health by assuring that a facility can perform quality mammography. The inspection revealed the following Level 1 finding at your facility:

Quality control records for the breast phantom were missing for a period of 6 weeks for the [REDACTED] Imaging Mammography units located in Rooms #1 and #2.

This problem is identified as a Level 1 finding because it identifies a failure to comply with significant MQSA requirements.

Because this condition may be symptomatic of serious underlying problems that could compromise the quality of mammography performed at your facility, it represents 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 Directed Plan of Correction; 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, MQSA standards; suspension or revocation of your facility's FDA certificate; or obtaining a court injunction against further mammography.

Mr. Wilbur Baggs

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It is necessary for you to act on this matter immediately. Please explain to this office in writing within fifteen (15) working days from the date you receive 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.

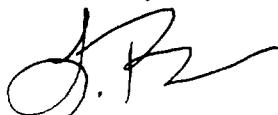
Your response should be sent to:

Food and Drug Administration
900 Madison Avenue
Baltimore, Maryland 21201
Attn: David J. Gallant
Compliance Officer

Finally, you should understand that there are many FDA requirements pertaining to mammography. This letter pertains only to findings of your inspection and does not necessarily address other obligations you may 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>.

If you have specific questions about mammography facility requirements or about the content of this letter, please feel free to contact Elizabeth A. Laudig at (410) 962-3591, extension 159.

Sincerely,



Lee Bowers
Director, Baltimore District