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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Central Region

Food and Drug Administration
Waterview Corporate Center
10 Waterview Blvd., 3rd Floor
Parsippany, NJ 07054

Telephone (973) 526-6007

May 30, 2003

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED
Mr. Gerald Mullen
Administrative Director
Beckett Diagnostic Center, LLC
101 Center Square Road
Swedesboro, New Jersey 08085

FILE NO.: 03-NWJ-06
Inspection ID NO.: 2221530004

Dear Mr. Mullen:

On April 15, 2003, a representative from the State of New Jersey 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 (U.S.C.), 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 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 at your facility at the close of the inspection:

- **Level 1: Your facility failed to perform weekly phantom image testing on your [redacted] mammography unit form October 2002 until April 2003. [See 21 CFR 900.12(e)(2)]**

- **Level 2 (Repeat): Your facility failed to perform an annual medical audit and outcome analysis for each individual radiologist's mammographic interpretations for which biopsies were requested, and for the interpretations of your facility as a whole in which biopsies were requested. [See 21 CFR 900.12(f)]**

- **Level 2: Your facility failed to use correct assessment categories for 3 of 5 random reports reviewed during your facility's inspection. [See 21 CFR 900.12(c)(1)(iv)]**

Because the continued 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, the MQSA standards;
- seeking to suspend or revoke your facility's FDA certificate;
- seeking a court injunction against your facility.

See 42 U.S.C. 263b(h)-(j) and CFR 900.12(j).

Based on the inspectional findings described in this letter, FDA has determined that your facility should be subjected to additional mammography review. The entity designated by FDA for this purpose is the American College of Radiology (ACR). The ACR will contact you regarding the selection of films for their review.

If FDA determines that the quality of mammography performed at your facility was so inconsistent with the MQSA and FDA regulations as to present a significant risk to individual or public health, FDA regulations authorize us to require your facility to notify patients and their referring physicians of the deficiencies presenting such risk and other relevant information.

If you choose to respond to the above violations, your response should include:

- 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;

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

- sample records that demonstrate proper record keeping procedures.

Please submit your response to Rosa L. Brown, Compliance Technician, Food and Drug Administration, New Jersey District, 10 Waterview Blvd, 3rd Floor, Parsippany, New Jersey 07054.

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,

Douglas I. Ellsworth

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District Director
New Jersey District Office

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