DEPARTMENT OF HEALTH AND HUMAN SERVICES

FEI: 1000512567
Facility ID:150185
Inspection ID #1501850014

Food and Drug Administration
Baltimore District Office
6000 Metro Drive
Suite 101
Baltimore, MD 21215-3215
Telephone: (410) 779-5454

03-BLT-09

March 18, 2003

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Joseph F. Branda, M.D., President
Laurel Diagnostic Imaging
Drs. Branda and Greyson, PA
9811 Mallard Drive
Suite 102-104
Laurel, Maryland 20708

Dear Dr. Branda:

A representative of the State of Maryland, acting on behalf of the Food and Drug Administration (FDA), inspected your facility on January 31, 2003. This inspection revealed a serious regulatory problem involving the mammography at your facility. Under the Mammography Quality Standards Act (MQSA) of 1992, which is codified in Section 263b of Title 42 of the United States Code (USC), 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 violations of the MQSA at your facility. These violations were identified on the MQSA facility inspection report and the document *"Important Information about Your MQSA Inspection"* that the inspector left with you at the close of the inspection. The violations are again identified below:

- **Level 1:** Your facility failed to document that weekly phantom quality control testing was performed on the following dates: 3/24/2002, 4/07/2002, 8/04/2002, 9/01/2002, 9/15/2002, 10/20/2002, 11/03/2002, 12/29/2002; **21 CFR 900.12(e)(2)**

- **Level 1:** Your facility failed to specify adequate procedures for machine infection control; **21 CFR 900.12(e)(13)**

- **Level 1:** Your facility failed to specify adequate procedures for consumer complaint collection and resolution; **21 CFR 900.12(h)**

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

Because these conditions may be symptomatic of serious underlying problems that could compromise the quality of mammography at your facility, they represent a serious 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, 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; 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; or suspension or revocation of your facility's FDA certificate

See 42 USC 263b(h)-(j) and 21 CFR 900.12

FDA may need to perform a Compliance Follow-up Inspection to determine that each problem at your facility has been corrected.

If you choose to respond to the above 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 steps you have taken, or will take, to **prevent the recurrence** of similar violations, including projected timeframes for implementing those steps;

3. sample records that demonstrate proper record keeping procedures. **(Note: Patient names or identification should be deleted from any copies submitted).**

Your response should be submitted to: Food and Drug Administration, 6000 Metro Drive, Suite 101, Baltimore, Maryland 21215, to the attention of Vinetta Howard-King, Compliance Officer.

Please send a copy of your response to:

Yun Chong, Mammography
Maryland Department of the Environment
Radiological Health Program
1800 Washington Boulevard, Suite 705
Baltimore, Maryland 21230

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/cdrh/mammography/index.html.

If you have technical 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,

Lee Bowers
Director, Baltimore District