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Irvine, California 92612-2445  
Telephone (949) 798-7600

## WARNING LETTER

**Certified Mail**  
**Return Receipt Requested**

March 6, 2001

Bruce Shragg, M.D.  
Chief of Radiology  
MPTF Toluca Lake Health Center  
4323 Riverside Drive  
Burbank, CA 91505

W/L Number: 24 - 01  
Inspection ID: 2082070006  
CFN: 20-30,700  
FEI: 3000204047

Dear Dr. Shragg:

We are writing to you because on December 18, 2000, your facility was inspected by a representative of the State of California acting in behalf of the U. S. Food and Drug Administration (FDA). This inspection revealed a serious regulatory problem involving the mammography at your facility.

Under a United States Federal law, the Mammography Quality Standards Act of 1992 (MQSA), 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 the following Level 1 findings at your facility:

- Level 1: Phantom QC records were missing for 6 weeks for unit #1 (a [REDACTED] machine, serial number [REDACTED]), located in the mammography room.
- Level 1: Mammograms were processed in processor #1 (a [REDACTED] machine, model [REDACTED]), located in the darkroom, when it was out-of-limits on nine (9) days.

Page Two of Three  
March 6, 2001

re: Warning Letter #24 – 01  
re: MPTF Toluca Lake Health Ctr.

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 problems are identified as Level 1 because they identify a failure to meet a significant MQSA requirement.

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, 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.

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 received this letter:

- the specific steps you have taken to correct all of the violations noted in this letter;
- each step your facility is taking to prevent the recurrence of similar violations; and
- please submit sample records that demonstrate proper record keeping procedures, if the findings relate to quality control or other records.

Please submit your response to:

Thomas L. Sawyer  
Director, Compliance Branch  
U.S. Food & Drug Administration  
19900 MacArthur Blvd.; suite #300  
Irvine, CA 92612-2445  
Phone: (949) 798-7600

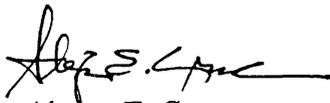
Finally, you should understand that there are many FDA requirements pertaining to mammography. This letter pertains only to findings of your inspection and does not necessarily address other obligations you have under the law. You may obtain general information about all of FDA's requirements for mammography 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>.

Page Three of Three  
March 6, 2001

re: Warning Letter #24 – 01  
re: MPTF Toluca Lake Health Ctr.

If you have more specific questions about mammography facility requirements, or about the content of this letter, please feel free to contact Beverly Thomas (MQSA Auditor) at telephone number (949) 798-7708.

Sincerely,



Alonza E. Cruse  
District Director

cc:

State of California  
Dept. of Health Services  
Radiological Health Unit  
550 South Vermont Avenue; Suite #601  
Los Angeles, CA 90020

Ms Priscilla F. Butler  
Director, Breast Imaging Accreditation Programs  
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