



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service  
Food and Drug Administration

g1375d

19900 MacArthur Blvd., Ste 300  
Irvine, California 92612-2445  
Telephone (949) 798-7600

## WARNING LETTER

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

June 8, 2001

Tito Nguyen, M.D.  
Medical Director of Mammography  
Kaiser Permanente Medical Center  
1011 Baldwin Park Blvd.  
Baldwin Park, CA 91706

W/L Number: 50 - 01  
Inspection ID: (below)  
CFN: (below)  
FEI: (below)

Dear Dr. Nguyen:

We are writing to you because on the following dates your mammography facilities located at the following locations

1011 Baldwin Park Blvd. Baldwin Park, CA 91706 Inspected on: May 8, 2001	Inspection ID: 1907020007 CFN: 20-30,143 FEI: 1000519263
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1550 Town Center Drive Montebello, CA 90640 Inspected on: May 18, 2001	Inspection ID: 1908190007 CFN: 20-30,153 FEI: 1000519253
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were 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 facilities.

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

- Level 1: The system to communicate results is not adequate because there is no system in place to provide timely lay summaries.

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re: Kaiser Permanente (various locations)  
re: Warning Letter Number 50 - 01

The specific problem noted above appeared on each of the MQSA Facility Inspection Reports which were issued to each of your facilities at the close of their inspection. This problem is identified as Level 1 because it identifies a failure to meet a significant MQSA requirement.

Because this condition may be symptomatic of serious underlying problems that could compromise the quality of mammography at your facilities, it represents 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 facilities are taking to prevent the recurrence of similar violations with additional emphasis on how **all** of your Kaiser Permanente health centers are going to prevent this Level 1 violation from occurring in the future; and
- please provide sample records that demonstrate proper record keeping procedures, if the findings relate to quality control or other records (Note: Patient names or identification should be deleted from any copies submitted).

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

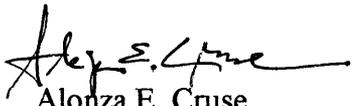
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the Mammography Quality Assurance Program, Food and Drug Administration, P.O. Box 6057, Columbia, MD 21045-6057 (1-800-838-7715) or through the Internet at <http://www.fda.gov>.

If you have 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