



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

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

WARNING LETTER

Certified Mail
Return Receipt Requested

June 8, 2001

Virginia Ambrosini, M.D.
Medical Director
Kaiser Foundation Hospital - Panorama City
Medical Group Administration
13652 Cantara Street
Panorama City, CA 91402

W/L Number: 47 - 01
Inspection ID: (below)
CFN: (below)
FEI: (below)

Dear Dr. Ambrosini:

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

43112 North 15 th Street West	Inspection ID: 1907690008
Lancaster, California 93534	CFN: 20-30,460
Inspected on: May 3, 2001	FEI: 1000519880

13640 Roscoe Blvd., North III	Inspection ID: 1906860008
Panorama City, California 91402	CFN: 20-30,141
Inspected on: May 15, 2001	FEI: 1000519265

13652 Cantara Street	Inspection ID: 1904960008
Panorama City, California 91402	CFN: 20-30,136
Inspected on: May 16, 2001	FEI: 1000519270

27107 Tourney Road	Inspection ID: 1908270007
Santa Clarita, California 92355	CFN: 20-30,154
Inspected on: May 17, 2001	FEI: 1000519252

were inspected by a representative of the State of California acting in behalf of the U. S. Food and Drug Administration (FDA). Each of those separate inspections revealed the same serious regulatory problem at each of those facilities.

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re: Kaiser Foundation (various locations)
re: Warning Letter Number 47 - 01

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 following Level 1 finding at all four of your facilities:

- Level 1: Your mammography facilities could not demonstrate, via documentation during the inspection, that the interpreting physician, [REDACTED], had an Operator-Supervisor Certificate in California. Without this Certificate, the physician is not licensed as a Radiologist in California.

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 all of 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 the violation 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;
- 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); and,

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- please further note that we are specifically requesting documentation that Dr. [REDACTED] that your facilities employ and/or did employ during each of the inspections, is currently licensed to practice medicine in your State of operation **and** possesses a valid and current Operator-Supervisor Certificate as a radiologist physician in your State of operation. We are requesting your explanation on how an individual is reading mammography results at four of your facilities without that individual being a licensed radiologist.

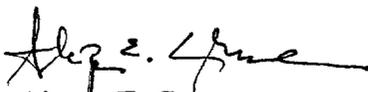
Please submit your response to:

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>.

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