



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

m3021n

1990 MacArthur Blvd., Ste 300
Irvine, California 92612-2445
Telephone (949) 798-7600

WARNING LETTER

OCT 6 1999

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

W/L 02-00

Arnold Vinstein, M.D.
Mammography Radiologist
Drummond Medical Group
1111 N. China Lake Blvd.
Ridgecrest, CA 92673

Inspection ID: 110973

Dear Dr. Vinstein:

We are writing you because on September 8th, 1999, your facility was inspected by a representative of the State of CA, acting in behalf of the Food and Drug Administration (FDA). This inspection revealed a serious regulatory problem involving the mammography at your facility.

Under a United States Law, the Mammography Quality Standards Act of 1992, 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 and level 2 findings at your facility:

- Level 1: The interpreting physician did not meet the requirement of being licensed by a State to practice medicine: [REDACTED]
- Level 2: There is no written procedure for handling consumer complaints at site Drummond Medical Group.
- Level 2: The interpreting physician did not meet the continuing education requirement of having completed a minimum of 15 CME credits in mammography in a 36 month period: [REDACTED]
- Level 2: The interpreting physician did not meet the continuing education requirement of having completed a minimum of 15 CME credits in mammography in a 36 month period: [REDACTED]

Level 2: The interpreting physician did not meet the continuing education requirement of having completed a minimum of 15 CME credits in mammography in a 36 month period: [REDACTED]

Level 2: The interpreting physician did not meet the continuing education requirement of having completed a minimum of 15 CME credits in mammography in a 36 month period: [REDACTED]

Level 2: The interpreting physician did not meet the continuing education requirement of having completed a minimum of 15 CME credits in mammography in a 36 month period: [REDACTED]

Level 2: The interpreting physician did not meet the continuing education requirement of having read or interpreted 960 patient examinations in a 24 month period: [REDACTED]

Level 2: The interpreting physician did not meet the continuing education requirement of having read or interpreted 960 patient examinations in a 24 month period: [REDACTED]
YAWITZ

Level 2: The interpreting physician did not meet the continuing education requirement of having read or interpreted 960 patient examinations in a 24 month period: [REDACTED]

Level 2: The interpreting physician did not meet the continuing education requirement of having read or interpreted 960 patient examinations in a 24 month period: [REDACTED]

Level 2: The interpreting physician did not meet the continuing education requirement of having read or interpreted 960 patient examinations in a 24 month period: [REDACTED]
[REDACTED]

Level 2: The interpreting physician did not meet the continuing education requirement of having read or interpreted 960 patient examinations in a 24 month period: [REDACTED]

Level 2: The interpreting physician did not meet the continuing education requirement of having read or interpreted 960 patient examinations in a 24 month period: [REDACTED]
[REDACTED]

Level 2: The interpreting physician did not meet the continuing education requirement of having read or interpreted 960 patient examinations in a 24 month period. [REDACTED]

The specific problems noted above appeared on your Facility Inspection Report, which was issued to your facility at the close of the inspection. 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 penalties up to \$10,000 for each failure to substantially comply with, or each day of failure to substantially comply with, the 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;
- ◆ equipment settings (including technique factors), raw test data, and calculated final results, where appropriate; and
- ◆ 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 written response to:

Thomas L. Sawyer
Director Compliance Branch
Food and Drug Administration
19900 MacArthur Boulevard, Suite 300
Irvine, California 92612-2445

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

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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 Robert W. Nicol at (949) 798-7667.

Sincerely,


Acting District Director