DEPARTMENT OF HEALTH & HUMAN SERVICES

940890

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 11, 2003

James Christion
Imaging Director
Daniel Freeman Marina Hospital
4650 Lincoln Blvd.
Marina del Rey, CA 90292-6306

W/L Number: 40 - 03
Inspection ID: 1665790009
CFN: 20-29,867
FEI: 1000518988
FACTS: 17557 - 0

Dear Mr. Christion:

On April 17, 2003, a representative for the State of California, acting on behalf of the Food and Drug Administration ("FDA") inspected your facility. This inspection revealed serious problems involving the conduct of mammography at your facility. Under the Mammography Quality Standards Act of 1992 ("MQSA"), which is codified in Section 263b of Title 42 of the United States Code, your facility must meet specific requirements to practice mammography. These requirements help to 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 noted on the MQSA Facility Inspection Report (*"Important Information about your Mammography Quality Standards Act (MQSA) Inspection"*) that the inspector left at your facility at the close of the inspection on April 17th. The inspection revealed four repeat Level 2, one Level 2, and one repeat Level 3 findings at your facility. These violations are identified below:

Level 2 - Medical audit and outcome analysis was not done for the facility as a whole. This is a violation of Title 21 Code of Federal Regulations section 900.12(f)(1). This is a REPEAT violation.

Level 2 - Medical audit and outcome analysis was not done separately for each individual. This is a violation of Title 21 Code of Federal Regulations section 900.12(f)(1). This is a REPEAT violation.

Level 2 - Medical audit and outcome analysis was not performed annually. This is a violation of Title 21 Code of Federal Regulations section 900.12(f)(2). This is a REPEAT violation.

Level 2 - There is no designated audit (reviewing) interpreting physician. This is a violation of Title 21 Code of Federal Regulations section 900.12(d)(1). This is a REPEAT violation.

Level 2 - Failed to produce documents verifying that the interpreting physician, [redacted] (6.5 CME's in 36 months), met the continuing education requirement of having taught or completed at least fifteen (15) category 1 continuing medical education units in mammography in thirty-six (36) months. This is a violation of Title 21 Code of Federal Regulations section 900.12(a)(1)(ii)(B).

Level 3 - The required personnel qualification documents were not available during the inspection . This is a violation of Title 21 Code of Federal Regulations section 900.12(a)(4). This is a REPEAT violation.

Because these violations may be symptomatic of serious underlying problems that could compromise the quality of mammography at your facility, FDA may take additional actions, including, but not limited to, the following:

- requiring your facility to undergo an Additional Mammography Review
- placing your facility under a Directed Plan of Correction ("DPC")
- charging your facility for the cost of on-site monitoring
- seeking civil money penalties of up to $10,000 for each failure to substantially comply with, or each day of failure to substantially comply with, MQSA standards
- seeking to suspend or revoke your facility's FDA certificate
- seeking a court injunction against your facility.

See Title 42, United States Code, sections 263b(h)-(j) and Title 21, Code of Federal Regulations, section 900.12(j).

You should respond, in writing, to FDA within fifteen (15) working days from the date you received this letter. 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 implementation of those steps; and,

3. please submit sample records that demonstrate proper record keeping procedures as it pertains to the said violations.

Note: patient names and other information that would likely reveal the patient's identity should be deleted from any copies of records you submit.

Your response should also specifically address why there are repeat violations which were not corrected from the previous inspection on April 29, 2002 . We are requesting why these repeat violations were not corrected prior to the inspection of April 17, 2003 and who, by name and title, had the responsibly & authority for implementing the correction. The year 2002 inspection was closed-out by us based upon a letter (dated July 10, 2002) we received from the State's sub-contracting agency (County of Los Angeles – Radiologic Branch). Your facility's letter was from a Ms [redacted] (chief operating officer) stating in part "***On May 29, 2002, Daniel Freeman Marina Hospital announced that it had begun the process of closure.***This letter shall serve as formal notification that there is a strong likelihood that this mammography equipment will be moving to Daniel Freeman Memorial Hospital.***".

Please submit your response to:

Scott Goff
Director (acting), Compliance Branch
U.S. Food & Drug Administration
19900 MacArthur Blvd.; Suite #300
Irvine, CA 92612-2445
Phone: (949) 798-7600

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, U. S. Food and Drug Administration, P.O. Box 6057, Columbia, MD 21045-6057 (telephone number: 1-800-838-7715) or through the Internet at http://www.fda.gov/cdrh/mammography/index.html

If you have additional or more specific questions about mammography facility requirements or about the contents of this letter, feel free to contact Scott Goff (the Compliance Officer assigned to this case) at telephone number 949-798-7644.

re: Daniel Freeman Marina Hospital
re: Warning Letter Number 40 – 03

Sincerely,

Alonza E. Cruse
District Director

cc:

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