DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

9128Id

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

WARNING LETTER

Certified Mail
Return Receipt Requested

May 22, 2001

John S. Link, M.D.
Medical Director
Pacific Coast Breast Center, A Medical Corporation
3445 Pacific Coast Highway
Suite #200
Torrance, CA 90505

W/L Number: 45 - 01
Inspection ID: 1834750007
CFN: 20-29,985
FEI: 1000519126

Dear Dr. Link:

We are writing to you because on May 1, 2001, 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: Mammograms were processed in processor #1 (a [redacted] machine, model [redacted]), located in the darkroom, when it was out of limits on at least five (5) days.

The specific problem noted above appeared on your MQSA Facility Inspection Report which was issued to your facility at the close of the 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 facility, 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.

In addition, your response should address the Level 2 findings that were listed on the inspection report provided to you at the close of the inspection. These Level 2 findings are:

- Level 2: Corrective action before any further examinations (for a failing image score, or a phantom background optical density, or density difference outside the allowable regulatory limits) was not documented for unit #1 (a [redacted] machine, model [redacted]) located in the mammography room.

- Level 2: Corrective actions for processor quality control failures were not documented, at least once, for processor #1 (a [redacted] machine, model [redacted]) which is located in the darkroom.

- Level 2: Failed to produce documents verifying that the interpreting physician, [redacted], (has zero continuing medical units [CME's] in 36 months) met the CME requirement of having taught or completed at least fifteen (15) category 1 CMEs in mammography in 36 months.

- Level 2: Failed to produce documents verifying that the radiologic technologist, [redacted], met the continuing experience requirement of having performed two hundred (200) mammography examinations in twenty-four (24) months.

- Level 2: Failed to produce documents verifying that the radiologic technologist, [redacted] (has seven CEU's in 36 months) met the continuing education requirement of having taught or completed at least 15 continuing education units in mammography in 36 months

- Level 2: Failed to produce documents verifying that the radiologic technologist, [redacted], met the continuing experience requirement of having performed two hundred (200) mammography examinations in 24 months.

- Level 2: Failed to produce documents verifying that the radiologic technologist, [redacted], met the continuing experience requirement of having performed two hundred (200) mammography examinations in 24 months.

- Level 2: Failed to produce documents verifying that the radiologic technologist, [redacted], (has 12½ CEU's in 36 months) met the continuing education requirement of having taught or completed at least 15 continuing education units in mammography in 36 months.

- Level 2: Failed to produce documents verifying that the radiologic technologist, [redacted], met the continuing experience requirement of having performed two hundred (200) mammography examinations in 24 months.

- Level 2: Failed to produce documents verifying that the radiologic technologist, [redacted], (has 13½ CEU's in 36 months) met the continuing education requirement of having taught or completed at least 15 continuing education units in mammography in 36 months.

- Level 2: Failed to produce documents verifying that the radiologic technologist, [redacted], met the continuing experience requirement of having performed two hundred (200) mammography examinations in 24 months.

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 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

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