DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
93673d

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

WARNING LETTER

Certified Mail
Return Receipt Requested

October 21, 2002

Saeed Yadegar, M.D.
Lead Interpreting Physician
Pioneer Medical Group, Inc. – Long Beach
2220 Clark Avenue
Long Beach, CA 90815-2521

W/L Number: 02 - 03
Inspection ID: 2245000001
CFN: 20-32,603
FEI: 3003802099
FACTS: 15185-0

Dear Dr. Yadegar:

We are writing to you because on September 10, 2002, your facility was inspected by a representative of the State of California acting on behalf of the Food and Drug Administration (FDA). This inspection revealed a serious regulatory problem involving the mammography at your facility.

Under the Mammography Quality Standards Act of 1992 (MQSA), 42 U.S.C. § 263b and the Quality Standards for Mammography set forth in Title 21, Code of Federal Regulations (C.F.R.), Part 900, 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 four Level 1 violations and five Level 2 violations at your facility:

Level 1 - Mammograms were processed in processor #1 (a [redacted] machine, model [redacted]), which is located in the mammography darkroom, when it was out of limits on at least 5 days. This is a violation of section 900.12(e)(1).

Level 1 - Processor quality control (QC) records in the month of August 2002 were missing on all twenty-three (23) days that mammographic examinations were being performed on patients for processor #1 (a [redacted] machine, model [redacted] or [redacted]) which is located in the mammography darkroom. This is a violation of sections 900.12(d)(2) and 900.12(e)(1).

Level 1 - Processor QC records were missing from May 2002 through September 10, 2002 for processor #1 (a [redacted] machine, model [redacted] or [redacted]) which is located in the mammography darkroom. This is a violation of sections 900.12(d)(2) and 900.12(e)(1).

Level 1 - Phantom QC records were missing for at least 4 weeks for unit #1 (a [redacted] machine, model [redacted], serial number [redacted]) which is located in the mammography room. This is a violation of section 900.12(e)(2).

Level 2 - Corrective actions for processor QC failures were not documented at least once for processor #1 (a [redacted] machine, model [redacted] or [redacted]) which is located in the mammography darkroom. This is a violation of section 900.12(e)(3)(ii).

Level 2 - Corrective action before further exams (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], serial number [redacted]) which is located in the mammography room. This is a violation of sections 900.12(e)(8)(ii) through (ii) and 900.12(d)(2).

Level 2 - The phantom QC is not adequate for unit #1 (a [redacted] machine, model [redacted], serial number [redacted]), which is located in the mammography room, because the operating level for background density was less than 1.20 . The background optical density was at this value on some weeks and months in the year 2001 while mammography examinations were being performed on patients. This is a violation of section 900.12(e)(2)(i).

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

Level 2 - Medical audit and outcome analysis was not done separately for each individual.* This is a violation of section 900.12(f)(1).

* Your facility presented outcome analysis for all of your Pioneer Medical Group facilities and all interpreting physicians in all of the different clinics / facilities. The outcome analysis should be performed separately for <u>each</u> facility as a whole and for <u>each</u> individual interpreting physician.

The specific problems noted above appeared on your MQSA 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 that may result in FDA imposing regulatory sanctions. These actions include, but are not limited

to, placing your facility under a Directed Plan of Correction (DPC) and/or charging your facility for the cost of on-site monitoring. Failure to correct these violations promptly could also cause FDA to seek 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, suspension or revocation of your facility's FDA certificate, or a court injunction against performing further mammography (see 42 U.S.C. §§ 263b(h) through (j) of the MQSA).

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

- please submit 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 (telephone number: 1-800-838-7715) or through the Internet at http://www.fda.gov

re: Pioneer Medical Group, Inc. – Long Beach
re: Warning Letter Number 02 – 03

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

Sincerely,

Alonza E. Cruse
District Director

cc:

Kathleen A. Kaufman, Director
County of Los Angeles
Department of Health Services
Radiological Management Health Unit
3530 Wilshire Blvd.; 9th Floor
Los Angeles, CA 90010-2310

Edward W. Gloor
Director and Health Physicist
Inspection Compliance and Enforcement
State of California
Department of Health Services
Radiologic Health Branch; Mammography Program
P.O. Box 942732, MS-178
Sacramento, CA 94234-7320