



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

m 3535m

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

WARNING LETTER

MAR 1 0 2000

Certified Mail
Return Receipt Requested

Lisa J. Peck, Mammography Consultant
Clinica Medica General – Huntington Park
6347 Pacific Boulevard
Huntington Park, CA 90255

W/L 33-00
Inspection ID: 1961540005

Dear Ms. Peck:

We are writing to you because on 9/28/1999, your facility was inspected by a representative of the state of California, 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 Federal law, the Mammography Quality Standards Act (MQSA) 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 finding at your facility:

Phantom QC records were missing for 9 weeks for unit 2, Bennett X-Ray Corp., 150G, room mammo

The specific problem noted above appeared on your MQSA Facility Inspection Report, which your facility received 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 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 performing further mammography.

In addition, there was one level-2 finding that was listed on the inspection report provided to you at the close of the inspection. This level-2 finding is:

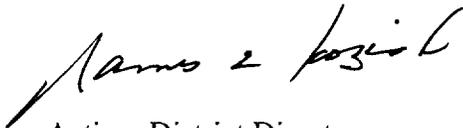
The processing speed (using the S.T.E.P. procedure) is greater than or equal to 65, but less than 80 for standard processing: processor 0000000001, Konica (Sakura), QX 130 or 130A or 130A Plus, room Mammo at site Clinica Medica General - Huntington Park

On December 10, 1999 you responded to the listed level-1 and level-2 above. Based on your response, we considered that your explanations and corrective actions were acceptable. The corrections you have implemented will be evaluated during your next inspection.

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/cdrh/dmgrp.html> <<http://www.fda.gov/cdrh/dmgrp.html>>.

If you have more specific questions about mammography facility requirements, or about the content of this letter, please feel free to contact Beverly Thomas at (949) 798-7708 or Minh Phan at (949) 798-7711.

Sincerely yours,



Acting District Director